UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE HEARTWARE INTERNATIONAL, INC. SECURITIES LITIGATION	No. 1:16-cv-00520-LLS **JURY TRIAL DEMANDED**

AMENDED CLASS ACTION COMPLAINT

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1. Lead Plaintiff St. Paul Teachers' Retirement Fund Association ("Lead Plaintiff" or "Plaintiff"), by its undersigned attorneys, brings this action under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and U.S. Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, on behalf of itself and all other similarly situated purchasers of the securities of HeartWare International, Inc. ("HeartWare" or the "Company") from June 10, 2014 through January 10, 2016, inclusive (the "Class Period").

2. Lead Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based on, among other things, the independent investigation of Court-appointed Lead Counsel Bernstein Litowitz Berger & Grossmann LLP. This investigation included, among other things, a review and analysis of: (i) HeartWare's public filings with the SEC; (ii) public reports and news articles; (iii) research reports by securities and financial analysts; (iv) economic analyses of securities movement and pricing data; (v) transcripts of HeartWare's investor calls; (vi) consultations with relevant experts; (vii) interviews with former HeartWare employees; and (viii) other publicly available material and data identified herein. Lead Counsel's investigation into the factual allegations contained herein is continuing, and many of the facts supporting the allegations contained herein are known only to the Defendants or are exclusively within their custody or control. Lead Plaintiff believes that further substantial evidentiary support will exist for the allegations contained herein after a reasonable opportunity for discovery.

I. PRELIMINARY STATEMENT

3. This case arises from misstatements and omissions made by HeartWare and its CEO, Defendant Douglas E. Godshall, about the safety and commercial viability of the Company's most important new product, a heart pump called the "MVAD." As detailed herein, HeartWare failed to heed directives by the U.S. Food and Drug Administration ("FDA") to remedy dangerous

deficiencies in its processes for manufacturing and testing its devices. Instead, HeartWare disregarded serious defects in MVAD, and implanted the flawed device in patients enrolled in a pivotal clinical trial. Defendants nevertheless stated that the Company fixed the defects found by the FDA, and repeatedly emphasized MVAD's purported commercial value, superior safety profile, and cutting edge technological enhancements. None of these statements were true. As a direct result of this misconduct, HeartWare's clinical trial of MVAD ended in disaster, with nearly half the patients experiencing serious adverse side effects, and the Company's stock price losing more than two-thirds of its value.

4. HeartWare manufactures ventricular assist devices, known as "VADs." A VAD is a heart pump that is implanted in patients suffering from heart failure. At all relevant times, HeartWare had a single commercialized product, known as "HVAD." While HVAD experienced significant growth after it was introduced in 2009, by the time the Class Period began in June of 2014, HVAD's revenue growth was grinding to a halt as concerns about the safety of VADs and their suitability for widespread use increased. In order to prosper amidst the leveling of demand for HVAD, HeartWare began to emphatically promote a newer, smaller, and, most importantly, safer VAD, called MVAD. Given the stagnated growth in the existing VAD market, HeartWare became increasingly reliant on the investor excitement it generated about MVAD to buoy the Company's stock price. Moreover, because the Company's chief competitor, Thoratec, was successfully developing newer and safer VAD technology during the Class Period, HeartWare faced mounting pressure to report positive news about MVAD.

5. Godshall repeatedly stated that MVAD was the most important driver of the Company's growth and future commercial success. For instance, Godshall told investors that MVAD represented "the biggest deal in the VAD space probably for the next three or four years,"

was "the pump that everyone is waiting for," and was the catalyst that would reignite HeartWare's stalled growth. According to Godshall, MVAD would "stimulate double-digit growth," and "will be a major driver of stronger growth in [] 2016, 2017, 2018[, and] beyond." Thus, Godshall repeatedly stated that MVAD was a key reason the Company was "most optimistic about the longer-term prospects for HeartWare."

6. Consequently, investors and analysts were intensely focused on Defendants' statements about MVAD. Analysts reported that the success of MVAD was the core of their investment thesis for HeartWare stock, stating that "[t]he long-term potential and pipeline at HeartWare is reliant on the company's development of MVAD," and "MVAD is key to [HeartWare's] long-term story" and "critical to HTWR's long-term growth trajectory."

7. By the time the Class Period began, HeartWare was close to beginning medical trials for MVAD in Europe (known as a "CE Mark trial"). The CE Mark trial was a critical first step in obtaining regulatory approval to market MVAD in Europe, which would then be followed by regulatory review in the United States and, ultimately, the commercial introduction of MVAD domestically. However, on June 3, 2014, one week before the Class Period began, HeartWare received a Warning Letter from the FDA directing it to remedy significant deficiencies in its manufacturing, testing, and validation processes at its only manufacturing facility, where it manufactured its VAD devices. Standards for testing and manufacturing medical devices are imposed by law. Strict compliance with those standards is not only essential to safeguarding the welfare of patients, but necessary to ensure the successful commercialization and marketing of a company's medical products. Importantly, testing and validation standards provide assurance to investors and doctors that statements about a device's efficacy or safety have a sound basis.

8. The Warning Letter raised questions about the process by which MVAD was tested and produced, and thus, the device's integrity. Recognizing the singular importance of MVAD to HeartWare's commercial success, Godshall stated that he was focused on the product, its safety profile, and remediating any manufacturing deficiencies that could impact it. For example, Godshall stated that HeartWare's "new Number 1 priority" was to "address those concerns of the FDA," emphasizing that "from the moment [the Warning Letter] arrived, it became our highest priority." Godshall assured investors he was personally overseeing HeartWare's remediation effort because he had to "sign off" on the Company's compliance with FDA standards before the CE Mark trial began.

9. Throughout the Class Period, Defendants repeatedly assured investors that HeartWare was successfully remediating the manufacturing, testing and validation deficiencies identified in the Warning Letter that related to MVAD. Among other things, Godshall stated that HeartWare had "made significant progress" in addressing the Warning Letter, and would resolve any problems "before we start any clinical activities [for MVAD] ***so that we are more than squeaky clean***" and "***bulletproof***." Similarly, Godshall emphasized "how buttoned up we are being on the MVAD, given this refresh we've gone through as a result of the warning letter."

10. Based on HeartWare's supposedly sound manufacturing, testing and validation procedures, Defendants also assured investors that MVAD's safety profile was strong. Specifically, Godshall stated that HeartWare's validation and testing procedures had shown that it could not cause MVAD to "thrombus," stating that "we frankly can't thrombus, no matter how hard we try in the MVAD." Pump thrombosis is a serious complication arising from the formation of an obstructive blood clot in the VAD, and is one of the leading adverse events associated with VADs. Pump thrombosis can lead to ischemic and hemorrhagic stroke, renal

failure, or even death. Defendants' assurances that MVAD was not prone to pump thrombosis were particularly important to investors because this adverse side effect was responsible, in part, for stagnant growth in the size of the VAD market as a whole. As both investors and Defendants knew, any VAD that elevated patients' risk of pump thrombosis beyond the incidence associated with existing VADs would not be commercially viable.

11. Defendants also stated that two aspects of MVAD were key differentiating features that enhanced the device's safety profile and set the product apart from its competition: its controller, which contained the device's alarm system, and its "qPulse algorithm," which allowed MVAD to adjust its pumping speeds and supposedly reduced adverse events. For example, with respect to the qPulse algorithm, HeartWare's lead clinical investigator told investors that the "***real game breaker*** for the MVAD is qPulse" because that feature has "go[ne] a long way to alleviating" adverse side effects associated with VADs. Godshall stated that MVAD's controller "has a tremendous number of advantages over other systems," including the supposedly enhanced alarm system that made the device safer by promptly alerting patients and doctors to any problems.

12. Based on all these purported advantages, Godshall repeatedly represented that MVAD was a "paradigm-changing" and "game-changing technology" that would propel HeartWare to new commercial success. Analysts credited Defendants' statements about MVAD's commercial strength, stating, "[we] believe that this product should lead to renewed share taking and revenue growth worldwide."

13. Lead Plaintiff's investigation has revealed that the true facts inside HeartWare were completely at odds with Defendants' public representations. Numerous former HeartWare employees with direct knowledge of the Company's operations reported that, contrary to Defendants' statements that HeartWare was successfully remediating the deficiencies identified

by the FDA, the Company's manufacturing, testing and validation processes remained severely deficient through the Class Period. As detailed herein, former HeartWare personnel explained that the Company did next to nothing to change its testing, validation, and quality control processes after receiving the Warning Letter. These processes were so deficient that the professionals charged with improving them reported that it would take years to actually remediate them. Moreover, HeartWare engineers had reported numerous problems with MVAD, some of which actually increased the risk of pump thrombosis, but these problems were ignored. As one former HeartWare executive who was responsible for testing and validating MVAD explained, "Because of undue haste and, at all times, the focus was only on getting the product out the door and never on – at least with regard to software and electronics – what does it take to establish a method of ensuring we have a safe product."

14. Indeed, while Defendants repeatedly touted MVAD's safety profile, including its purported resistance to pump thrombosis, the true facts inside HeartWare told a different story. In reality, HeartWare executives identified several issues with MVAD that increased patients' risk, including the device's propensity to cause pump thrombosis. For instance, HeartWare executives discovered, but failed to remediate, significant malfunctions in MVAD's software responsible for ensuring that the pump's internal rotor, called an "impeller," did not strike the body of the pump and cause potentially fatal blood clots. Similarly, HeartWare personnel observed and reported that the controller's "suction alarm," which notifies patients and doctors when the pump is creating an imbalance of pressure in the heart that could induce pump thrombosis, was defective and would trigger only under extreme conditions. Defects in MVAD's suction alarm were particularly serious because, as Godshall acknowledged after the Class Period, the pump's design made it "more prone

to suction than HVAD." Notwithstanding the fact that MVAD was "prone" to suction, the defect in the pump's suction alarm went unremediated.

15. Defendants' statements concerning MVAD's qPulse algorithm also departed from reality. Contrary to Defendants' representations that the qPulse algorithm enhanced patient safety and gave MVAD a distinct advantage in the marketplace, the algorithm caused MVAD to pump blood out of the heart too quickly, which significantly increased the risk of pump thrombosis. While the controller's "suction alarm" should have alerted patients within minutes to the dangerous condition caused by the faulty qPulse algorithm, because that alarm was defective, this condition was allowed to persist in patients for weeks or even months at a time – a confluence of defects that put patients in serious jeopardy.

16. As a former high-ranking HeartWare executive explained, many of the defects in MVAD – which were so serious that they ultimately required the Company to halt the critical CE Mark trial – "were known early on and occurred early in the development phase," including "the suction alarm, the algorithms, the qPulse, displays that were blank or showed gibberish – those were problems that dogged the project throughout." And even before the Class Period began, these problems were discussed in meetings that Godshall attended, and were reflected in numerous meeting minutes he received.

17. Notwithstanding these severe problems, HeartWare management proceeded to rush MVAD to marketplace. On July 20, 2015, HeartWare announced that it had completed the first implant in the CE Mark trial.

18. Just six weeks later, investors were blindsided by a revelation that called the veracity of Defendants' prior statements into serious question. On September 1, 2015, HeartWare announced a highly dilutive transaction with another company named Valtech Cardio Ltd.

("Valtech"), which was in a different line of business than HeartWare. Under the terms of the transaction, HeartWare agreed to purchase Valtech with 4.4 million shares of HeartWare stock, which amounted to 25% of the Company's equity value, with milestones that could require HeartWare to pay up to 35% of its equity value in stock.

19. The market immediately questioned why – if Defendants' positive statements concerning MVAD were true – the Company would agree to give up as much as 35% of its equity value when MVAD was approaching regulatory approval, a development that would likely cause the Company's stock price to increase meaningfully as its "game-changing" product entered the marketplace. Analysts reported that the announced transaction cast doubt on HeartWare's prior statements concerning MVAD, writing that "it's unclear to us why HTWR management would dilute its shares by up to 35% if it were bullish on . . . MVAD."

20. In response to the announcement of the Valtech transaction, HeartWare's stock price sharply declined on extremely heavy volume, falling from $81.81 to $64.82, or 21%, in a single trading day. To stem any further decline, Defendant Godshall flatly denied that the Valtech transaction signaled that there were problems with MVAD, stating that "we are only doing this because of our confidence in our VAD portfolio and pipeline, not because we are concerned about prospects of growth for VADs or concerned about prospects for our portfolio specifically." Indeed, Godshall stated that HeartWare was "quite delighted" with MVAD's performance in the CE Mark trial.

21. Soon after the Company announced the Valtech transaction, HeartWare was confronted with deeply troubling facts further showing that MVAD bore no resemblance to the device the Company and Godshall had repeatedly described to investors. In particular, in the first 11 patients implanted with MVAD in the CE Mark trial, there were three incidents of pump

thrombosis – the dangerous adverse event that the market was concerned about. These adverse events had occurred at a rate of more than 27%, which was vastly in excess of prior reported incidence rates.

22. Specifically, the 27% incidence rate was between ***7 to 13 times greater*** than the 2-4% rate observed in prior studies of competing VADs that fueled market optimism. Equally disturbing, these pump thrombosis events had occurred unusually quickly after device implantation, further indicating that something was fundamentally amiss with MVAD. In particular, MVAD patients experienced pump thrombosis within three months, at the most, after pump implantation. By contrast, HeartWare's own existing VAD had demonstrated a median time to thrombosis of approximately 8 months after implantation, while other devices had exhibited an even longer time to thrombosis of 18.6 months. Thus, HeartWare's data indicated that MVAD not only failed to deliver the leap forward in safety over existing VAD technology the Company had promised, but, in fact, appeared to be ***materially more dangerous*** than existing devices.

23. On October 12, 2015, analysts reported rumors that HeartWare had experienced a cluster of adverse events in the early stages of its CE Mark trial. In response to this market speculation, HeartWare was forced to announce on October 12, 2015 that it was investigating "reported adverse events in certain clinical trial patients" who had been implanted with MVAD. The Company further announced that given its investigation into those adverse events, enrollment in the CE Mark trial, which had been briefly paused in September, might not resume as expected. HeartWare shares quickly plunged nearly 30%, falling from $50.07 per share on October 9, 2015 (the last trading day before October 12) to $35.21 per share on October 13, 2015, on heavy volume.

24. However, rather than inform the market about the extremely high rate of pump thrombosis it had observed, HeartWare did not disclose the nature or number of adverse events. Instead of disclosing this critical information, the Company attempted to mollify the market by falsely reassuring investors that the unspecified advserse events were "typical of those seen in other clinical trials for ventricular assist devices" – when, in reality, the incidence and rapid onset of the adverse events was highly unusual. Similarly, Godshall falsely assured investors that "our initial experience [in the CE Mark trial] has us more convinced than ever that the MVAD will be extremely successful in the clinic and ultimately in the marketplace," when, in truth, the clinical data indicated that MVAD's commercial viability was severely jeopardized.

25. On January 11, 2016, investors finally learned the full truth about MVAD. That day, Godshall announced that nearly half of the patients enrolled in the CE Mark trial experienced pump thrombosis. Moreover, Godshall admitted that the Company's dangerously defective qPulse algorithm and alarms – the same features he had touted as key differentiating aspects of MVAD – actually increased the risk of pump thrombosis. As noted above, the qPulse algorithm caused MVAD to pump blood out of the heart too quickly, generating clots that led to pump thrombosis, while the controller's defective suction alarm failed to alert patients, allowing this condition to persist in patients for weeks and months at a time.

26. HeartWare was forced to indefinitely suspend the CE Mark trial while seeking to repair both its qPulse algorithm and its "suction alarm detection system," efforts the Company expected would take at least "several months." The Company also acknowledged that, given the extent of the remediation required, it might not be able to resume the CE Mark trial it had already initiated, but would have to restart the clinical trial process from the very beginning. In other words, the key driver of the Company's future growth was an unmitigated disaster, and was now

sidelined indefinitely. In response to this news, investors immediately abandoned HeartWare stock. HeartWare shares plunged more than 35% in a single day, falling from $40.84 per share on January 11, 2016 to $26.50 per share on January 12, 2016, on extremely heavy volume.

27. In all, the disclosure of the true facts concerning MVAD caused massive losses to investors. HeartWare shares fell nearly 68%, from $81.81 per share at the close of trading on September 1, 2015, to $26.50 per share at the close of trading on January 12, 2016.

28. To date, the FDA has still not lifted the Warning Letter. Nor has HeartWare restarted the MVAD trial.

II. PARTIES

A. Lead Plaintiff

29. On April 11, 2016, the Court appointed St. Paul Teachers' Retirement Fund Association ("St. Paul Teachers'") as Lead Plaintiff. St. Paul Teachers' is a non-profit organization formed in 1909 that provides retirement, survivor, and disability benefits to public school educators in St. Paul, Minnesota. As of June 30, 2015, St. Paul Teachers' had assets of over $1 billion under management. St. Paul Teachers' purchased HeartWare common stock at artificially inflated prices during the Class Period as set forth in its certification previously filed with the Court, and was damaged thereby.

B. Defendants

30. Defendant HeartWare is a medical device company that develops and manufactures implantable heart pumps, called "ventricular assist devices" or "VADs," used to treat patients suffering from heart failure. HeartWare is headquartered in Framingham, Massachusetts. The Company's common stock is traded on the Nasdaq Stock Market ("Nasdaq") under the symbol "HTWR."

31. Defendant Douglas E. Godshall ("Godshall") has been President and Chief Executive Officer of HeartWare since September 2006, and became a director of the Company in October 2006. As discussed below, Godshall made numerous false and misleading statements and omissions of material fact, including on conference calls with analysts and investors and in HeartWare's public SEC filings.

III. FORMER HEARTWARE EMPLOYEES

32. Certain of the Complaint's allegations are based on information provided by former HeartWare employees interviewed by Lead Counsel.

33. Former Employee 1 was HeartWare's Director of Program Management from June 2008 through April 2014, and was a member of HeartWare's leadership team, reporting first to the Company's Chief Scientific Officer, Jeff LaRose, and then to its Senior Vice President for Research, Development, and Quality, Mark Strong.

34. Former Employee 2 was one of HeartWare's most senior software engineers throughout the Class Period.

35. Former Employee 3 was a contractor at HeartWare's Miami Lakes Facility from October 2014 to July 2015. Former Employee 3 served as a "CAPA" Manager[1] at HeartWare. In this capacity, Former Employee 3 was directly responsible for reviewing HeartWare's purported efforts to address the manufacturing, validation, and testing deficiencies identified in the Warning Letter.

[1] "CAPA," an acronym for "corrective and preventative action," is an essential part of quality control management that concerns the identification of "root causes" of defects and risks, and the development of processes for remediating those defects or risks. The FDA requires that medical device companies develop and maintain a CAPA process within their quality management system. *See* 21 C.F.R. 820.11.

36. Former Employee 4 was HeartWare's Program Manager for FDA 483 Warning Letter Remediation for Non-Product Software at the Company's Framingham headquarters from March to August 2014. Former Employee 4 was brought in specifically to address the deficiencies in HeartWare's quality assurance and manufacturing processes regulators identified, first in the Form 483 issued to the Company and then the Warning Letter.

37. Former Employee 5 was a Validation and Verification Tester at HeartWare from August 2012 to March 2015, and personally performed validation and verification testing on MVAD, including its controller. Former Employee 5 directly reported to the Engineering Group Lead in the Medical Device Design Verification department, and Former Employee 5's work, including problems he reported with MVAD, was reviewed by HeartWare's most senior engineering executives, including Jonathan Eagle, the Company's Principal Electronics Engineer, and Sanjeev Pandya, Director of Research and Development.

38. Former Employee 6 was employed by HeartWare as a Clinical Specialist in Germany, one of the Company's major clinical sites, from May 2010 until May 2015. Former Employee 6 reported directly to the Territory Manager for HeartWare. As a Clinical Specialist, HeartWare tasked Former Employee 6 with providing training to hospital staff regarding the Company's devices and, importantly, ensuring that implantation surgeries were executed properly.

IV. JURISDICTION AND VENUE

39. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act. Venue is proper pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). HeartWare common stock trades on the Nasdaq, which is located in this District, and acts giving rise to the

violations complained of herein, including the preparation and/or dissemination of materially false and misleading statements, occurred in this District.

40. In connection with the acts alleged in this Complaint, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including without limitation the mails, interstate telephone communications, and the facilities of the national securities exchanges.

V. SUMMARY OF THE FRAUD

A. MVAD Was the Key Driver of HeartWare's Growth, and the Focus of Management and Investor Attention Throughout the Class Period

41. HeartWare develops and manufactures miniaturized implantable heart pumps, or VADs, to treat patients suffering from heart failure. The Company's sole commercialized product, the HeartWare Ventricular Assist Device or "HVAD," is a continuous flow blood pump that is implanted adjacent to the heart. HeartWare operates only one manufacturing facility, which is located in Miami Lakes, Florida ("Miami Lakes Facility").

42. VADs are used to partially or completely replace heart function in patients whose native heart's pumping power is weaker than normal, generally through the weakening or improper functioning of the left ventricle. HVAD is supposed to work by supporting the weak left ventricle and providing additional blood flow. A key component of HVAD is the "controller," which is positioned outside the body and regulates and monitors HVAD's pump, as shown in Figure 1, below.

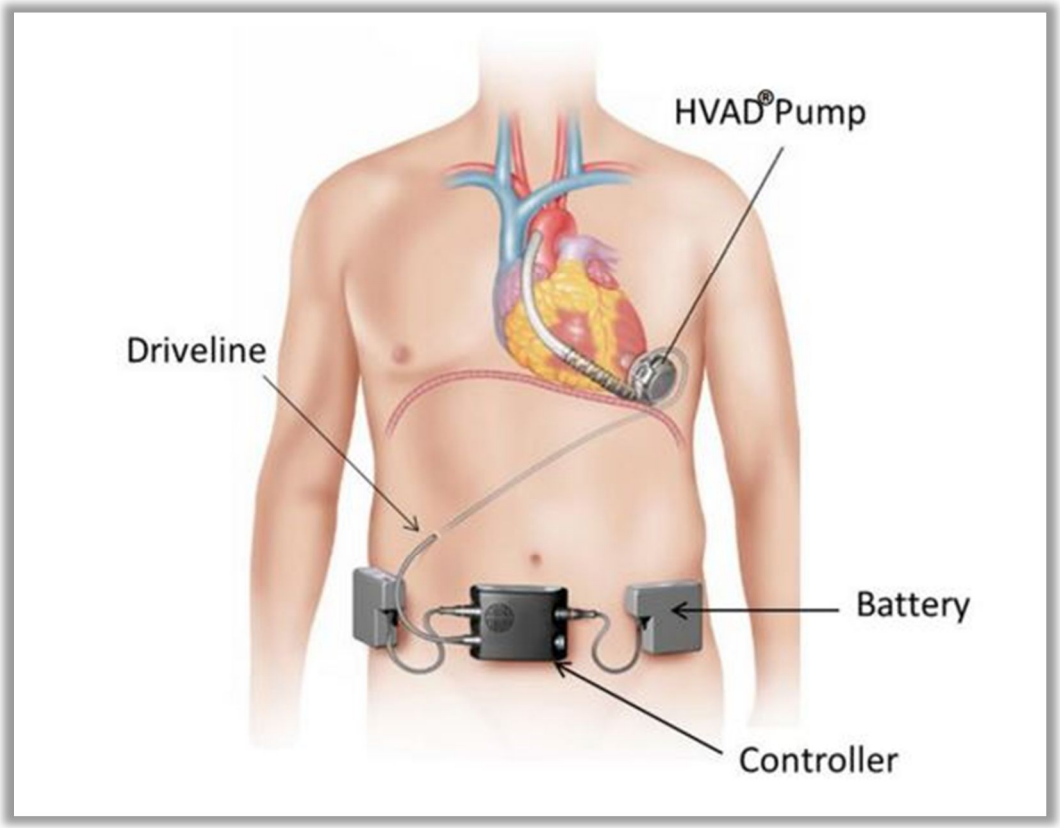

Figure 1.

43. HVAD experienced substantial market growth after its introduction into the market in 2009. However, as illustrated in Figure 2 below, by the beginning of 2014, that growth plateaued, as HVAD, and the VAD market generally, suffered a series of setbacks arising from increasing concern among doctors and regulators about the relative safety of VADs.

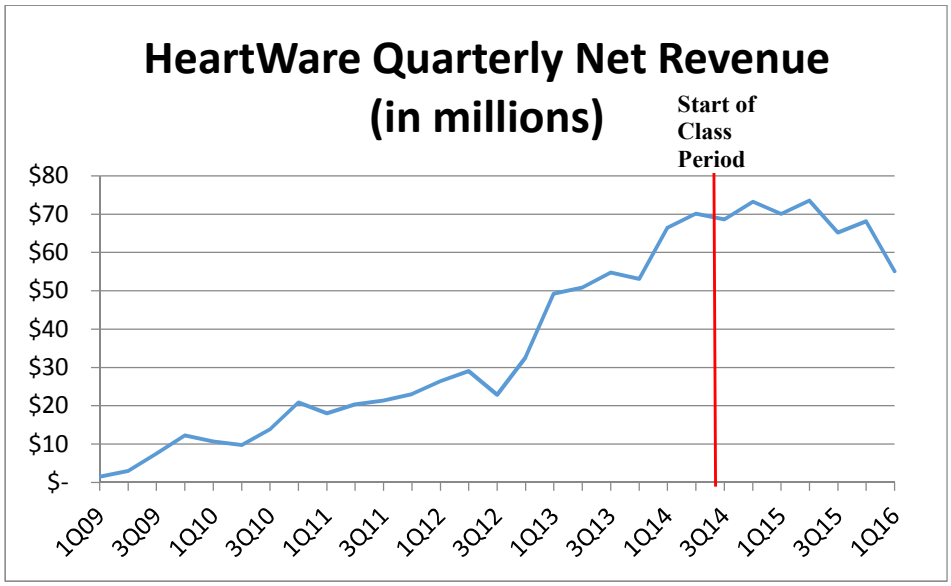

Figure 2.

44. First, a November 2013 article in the widely-read *New England Journal of Medicine* ("*NEJM*") showed significantly increased risk of pump thrombosis associated with HVAD's chief competitor, Thoratec's HeartMate II. This article reported that, while HeartMate II had shown an incidence of pump thrombosis between 2-4% in prior pivotal trials and postmarketing approval studies, HeartMate II was associated with an approximately 8% pump thrombosis rate in more recent data. As Godshall explained to investors, the publication of these data "spooked a lot of people because of adverse events" and HeartWare "certainly saw in the beginning of [2014] a reluctance to refer patients in part because of this *New England Journal* article and the aggregate adverse event profile." Analysts echoed Godshall's assessment, with Canaccord reporting that the "NEJM article on HM2 thrombus concerns has had a drag on patient referrals" for HVAD, and Credit Suisse reporting that they "anticipate[d] continued softness on NEJM-related thrombus concerns."

45. Second, also in November 2013, the Centers for Medicare and Medicaid Services ("CMS") – the agency responsible for making coverage determinations for these two market-

dominating government payors – changed important coverage policies that adversely affected HVAD. CMS tightened the criteria under which a patient could be listed as "awaiting heart transplantation." HVAD had been approved as an interim therapy for patients who were awaiting transplants, but not as an ultimate, or "destination," therapy for those who would require VAD assistance indefinitely. Because many potential patients could no longer be listed as "awaiting transplantation," CMS would no longer consider them candidates for HVAD and would not cover the cost of implantation. As Godshall explained, "It is increasingly difficult to compete with the national coverage determination [a coverage policy issued by CMS] that short-term bridge population [*i.e.*, patients awaiting transplant] is constrained, and even a lot of patients who used to be bridge decision are now just getting lumped into destination therapy since physicians and hospitals don't want to run any risk with CMS or payers. That has put downward pressure on the bridge segment."

46. Analysts identified both the November 2013 *NEJM* article and CMS decision as causing significant stagnation in HVAD's growth and the growth of the VAD market generally, and openly questioned "what can reinvigorate [the] LVAD market." As Leerink analysts explained,

> In 2014, we estimate that the U.S. LVAD market slowed to mid-single-digit implant volume growth – the slowest growth year since before THOR's [OP] HeartMate II BTT launch in early 2008, after which the LVAD market grew strong double-digits through 2013. While 2014 was impacted by very specific headwinds – notably a change in CMS' National Coverage Determination (NCD) and a NEJM article highlighting increasing rates of thrombus with THOR's HeartMate II initially published in late 2013 – this dramatic deceleration has raised some questions as to what can reinvigorate LVAD market growth in the near-term.

47. In response to the stalled growth of the VAD market, and HVAD specifically, Defendants put increasing emphasis on a new and purportedly safer device HeartWare had been developing, called MVAD. As HeartWare stated in filings with the SEC, "The MVAD System is

based on the same technology platform as the HVAD System," but is significantly smaller, at less than one-half the size of HVAD. According to the Company, MVAD would require less invasive surgery than HVAD and allow HeartWare to treat a greater number of patients at earlier stages of heart disease.

48. HeartWare billed MVAD as a "paradigm-changing" and "game-changing technology" that would reinvigorate the Company's stalled growth and propel the Company's commercial success to new heights. Throughout the Class Period, Godshall told investors that MVAD represented "the biggest deal in the VAD space probably for the next three or four years" and had "incredible upside potential." Godshall also stated that enthusiasm for MVAD, both inside the Company and among medical practitioners is "through the roof" and had "never been higher." Godshall stated that MVAD was "the pump that everyone is waiting for" and was a key reason Defendants were "most optimistic about the longer-term prospects for HeartWare." Indeed, Godshall stated that MVAD "will stimulate double-digit growth" and "will be a major driver of stronger growth in [] 2016, 2017, 2018[, and] beyond." Godshall acknowledged that he heavily promoted MVAD as a dramatic catalyst for HeartWare, calling himself "the global cheerleader for MVAD."

49. Godshall and HeartWare emphasized the superior safety profile of its next-generation MVAD device as the catalyst for reigniting market growth. As Godshall explained, "I think ultimately what will drive those inflection points for MVAD . . . . MVAD will have a materially lower adverse event profile." Godshall explained that between MVAD and Thoratec's next-generation VAD, called HeartMate III, the "across the board drop in adverse events for VADs" would "be quite stimulative to the market."

50. Given Defendants' positive statements about MVAD and how critical MVAD was to HeartWare's success, analysts and investors viewed MVAD as the principal basis of their investment in HeartWare. William Blair analysts noted, for instance, that "[t]he long-term potential and pipeline at HeartWare is reliant on the company's development of MVAD." Barclays analysts likewise noted that "[a] high teen's growth rate [for HeartWare] globally will also likely not be possible without approval of MVAD." Leerink analysts similarly stated, "MVAD is key to [HeartWare's] long-term story" and "critical to HTWR's long-term growth trajectory." Likewise, Canaccord analysts stated, "HTWR's medium and long-term growth prospects are largely tied to MVAD," explained that they "believe[d] MVAD could prove to be more of a game-changing device than" any competing VADs, and opined that "if MVAD achieves the promise of lowering stroke and bleeding risk at the same time" – a promise that depended, in part, on the success of MVAD's qPulse algorithm – "it could ultimately become the market leading VAD."

51. Analysts' models of HeartWare stock made clear that the Company's value was largely a function of MVAD's commercial promise. For instance, in an October 13, 2015 report, Credit Suisse analysts noted that their price target for HeartWare stock fell from $90 per share assuming MVAD received regulatory approval to only $34 if regulators failed to approve the device. These analysts opined that without MVAD, HeartWare would lose 50% of its projected market share.

52. In light of MVAD's obvious importance to HeartWare, Godshall assured investors that he was keenly focused on the details of its development and ultimate commercialization. On an October 30, 2014 earnings call, for example, Godshall told investors that he ***personally*** "walked around yesterday and asked everybody who could have possibly given me bad news [about MVAD] . . . . And everybody said 'on track.'" Likewise, on an October 29, 2015 call with

investors, Godshall claimed that he spent "10 hours yesterday reviewing an impressive spectrum of both old [MVAD] test data, new [MVAD] test data." Investors were comforted by Godshall's representations that "the global cheerleader for MVAD" was intimately familiar with the steps MVAD took on the path towards commercialization.

53. The most critical step in MVAD's journey to the market was its enrollment in clinical trials with both U.S. and foreign regulators that if successfully completed, would allow HeartWare to market and sell the device. At the start of the Class Period, HeartWare announced that it would first enroll MVAD in an international "CE Mark study" to obtain international marketing approval, followed shortly thereafter by a U.S. study to obtain marketing approval from the FDA. A "CE Mark" is the European equivalent of obtaining FDA approval, and indicates that a device has met the safety and other requirements to be approved for sale in the European Union.

54. Godshall stated that these clinical trials "are of critical importance long term for the Company," and investors agreed. Wells Fargo analysts stated, "***Over the course of 2015, we believe HTWR's stock will be driven largely by how well the initial MVAD implants in [the CE Mark trial] perform***."

B. The FDA's Warning Letter Alerted Defendants to Serious Deficiencies in MVAD's Manufacturing, Testing, and Validation Processes

55. The market for HeartWare's MVAD comprises heart-disease patients – a particularly vulnerable population. Given that patients' lives may likely depend on the safety and efficacy of the Company's devices, HeartWare's strict compliance with the FDA's manufacturing standards and device testing and validation practices was critical. The Company was required to comply with FDA quality-control standards, including current Good Manufacturing Processes ("cGMP"). Among other things, these standards set forth testing and validation processes that provide a basis for assessing whether the device functions properly, is manufactured correctly, and

is prone to adverse side effects. As HeartWare acknowledged, failure to comply with the FDA's regulations may result in "fines, injunctions, civil or criminal penalties, or other sanctions." Moreover, as HeartWare understood, failure to comply with FDA regulations could result in delayed approval, or even denial, of HeartWare's applications to market their experimental devices, including MVAD.

56. On January 13, 2014 through January 24, 2014, the FDA conducted a multi-day inspection of HeartWare's Miami Lakes Facility, where both HVAD and MVAD are manufactured. The FDA's inspection uncovered numerous deficiencies in HeartWare's manufacturing, testing, and validation processes resulting in significant violations of cGMP and applicable FDA regulations. As a result, investigators concluded that HeartWare's HVAD was "adulterated," as defined in the Food, Drug, and Cosmetic Act, *i.e.*, it bears, contains, or was prepared or held under conditions that may render the device "injurious to users." Shortly thereafter, the FDA issued HeartWare a Form FDA 483, a document that lists inspectors' deficiency findings and communicates their concerns.

57. Shortly before the beginning of the Class Period, on June 2, 2014, the FDA sent HeartWare a Warning Letter ("Warning Letter") – to the attention of Godshall – explaining that HeartWare's responses to the deficiencies identified in the Form FDA 483 were, to date, inadequate. Importantly, FDA guidance provides that Warning Letters are issued only "for violations of ***regulatory significance***, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected."

58. The Warning Letter reiterated that the "facilities or controls" employed at the Miami Lakes Facility "are not in conformity with the current good manufacturing practice (cGMP)

requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820." The FDA provided a non-exclusive list of specific violations, which included:

- "Failure to establish and maintain procedures for implementing corrective and preventive action" in light of prior serious problems, including ***serious problems related to HVAD controllers***. In other words, HeartWare failed to put in place and enforce an adequate process for identifying the "root causes" of defects and risks in its devices, including its controllers, and developing a process for remediating those defects or risks. Among other things, when HeartWare actually took remedial action, it failed to adequately test and validate those actions to make sure they were safe and effective.
- "Failure to establish and maintain procedures for validating the device design." In other words, HeartWare failed to establish uniform, consistent, and objective procedures for FDA-required testing to confirm that the design of its devices conform with patients' needs and the device's intended use, *i.e.*, to confirm that the device is properly designed to do what it is supposed to do.
- "Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i)." In other words, HeartWare failed to adequately test the software it used to control the machines responsible for assembling and testing its devices, creating the risk that the machines would improperly manufacture and assemble the devices or that the Company's testing would be inaccurate.
- "Failure to maintain a record of the investigation by the formally designated unit when an investigation is made," as the Company "did not document the likely or potential root cause or document an attempt to obtain the complete nature and details of at least 10 complaints which were submitted to FDA as MDR [medical device reporting] events." In other words, HeartWare failed to adequately document problems with its devices and the Company's investigation into those problems.

59. The Warning Letter raised particular concerns that HeartWare had not adequately addressed severe manufacturing and validation problems, even when those problems were brought to HeartWare's attention by way of reports of patient injury or death. For example, HeartWare failed to rectify manufacturing problems with the HVAD controller, despite receiving at least 27 complaints between February 2010 and November 2013 of controller failure, 6 of which involved patient death or serious injury. Likewise, the Company failed to rectify manufacturing deficiencies

resulting in loose HVAD "driveline connectors" – a component that connects the controller to the pump – despite receiving numerous patient complaints alerting HeartWare personnel to this issue.

60. The Warning Letter notified HeartWare – and Godshall in particular – that "You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the [FDA] without further notice." Moreover, the FDA warned that other proposed devices (including MVAD) "will not be approved until the violations have been corrected."

61. Because the Warning Letter focused on deficiencies in HeartWare's core manufacturing, testing, and validation processes, HeartWare recognized that the Warning Letter had serious negative implications for MVAD, especially since MVAD was, according to HeartWare, "based on the same technology platform" as HVAD, and was manufactured at the same facility. As Godshall told investors on the first day of the Class Period, "We are doing an assessment just to make sure if the FDA didn't like some stuff we did with HVAD, let's make sure that we're not doing the same stuff they didn't like with MVAD."

62. Shortly thereafter, on HeartWare's July 31, 2014 second quarter earnings call, an analyst asked Godshall, "[W]hat aspects of the warning letter impact MVAD specifically?" Godshall acknowledged that the Warning Letter would require, among other things, remediation of MVAD's validation, documentation, and testing processes. Godshall told investors that in light of the Warning Letter, HeartWare would need to "make sure that everything that we used to test and validate MVAD is up to standard" so that "there is no question about the integrity of the test reports that we have in-house."

63. Godshall characterized the Warning Letter, and "subsequent communication" with the FDA, as "impact[ing] every aspect of the Company," and specifically those processes utilized in MVAD's development and production.

> The overall theme of the FDA audit and then subsequent communication with us is both make sure you're buttoned up on your documentation, make sure you're buttoned up on your validations. And then in a specific area of validation, make sure you have specifically validated any of the equipment that's used to produce your product or measure your product and the like. And so there's – that can cover a wide array of things that can be measuring equipment . . . . So, recognizing a need to ensure that when we submit the document to the FDA, that if they have just said make sure all your equipment is validated, ***we'd better make sure all of our equipment is validated for MVAD***.

64. Throughout the Class Period, Godshall told investors that HeartWare was wholly focused on remediating the deficiencies identified in the Warning Letter. Godshall stated that HeartWare's "new Number 1 priority" was to "address those concerns of the FDA," and "mitigating our Warning Letter" was "now our most important project." Godshall further reassured investors that "from the moment [the Warning Letter] arrived, it became our highest priority. We immediately began to shift energy, attention, and resources to address the observations." In fact, Godshall stated that the Warning Letter and MVAD were HeartWare's top two priorities: "While the Company's clear number one objective is to address the warning letter as expeditiously as possible, the MVAD is a very close number two in terms of organizational attention and commitment."

65. Godshall also explained to investors that he was personally responsible for ensuring that MVAD was compliant with all pertinent regulations before any clinical trial activity could begin. "I have to sign off when we go into a new country with a new device that we are fully compliant with all the regulations and standards," and, "given what we are going through with the FDA, where they're asking us to basically improve our systems and processes on various areas,"

the Company, and Godshall in particular, would "***make sure that we're pristine***. ***Our validations are perfect***," before MVAD trials began.

66. Analysts were comforted by Godshall's representations that he was taking a hands-on approach to tackling the Warning Letter and was closely monitoring the Company's efforts. For instance, Canaccord analysts cited with approval "management['s] comment[s] that they are conducting a deep dive into the quality control systems and manufacturing processes of the MVAD system to ensure that there are no issues that the FDA may find objectionable."

C. HeartWare Assured Investors that It Was Successfully Remediating the Deficiencies Identified in the Warning Letter and that MVAD Was a Safe, "Paradigm-Changing" Technology

67. To assuage the market's concern about the Warning Letter's impact on MVAD, and reassure investors that MVAD was indeed the "game-changing" advancement they touted it as, Defendants made a series of materially false and misleading statements throughout the Class Period. In the time between the Company's announcement that it received the Warning Letter (on June 10, 2014) and the start of the CE Mark trial (on July 20, 2015), Defendants made materially false and misleading statements designed to assure the market that HeartWare was successfully remediating the deficiencies identified in the Warning Letter and that the Company's now-robust testing and validation processes demonstrated that MVAD had a highly favorable safety profile, particularly with respect to pump thrombosis, an adverse event that as described above, was of foremost concern to investors. As detailed below, these materially false and misleading statements principally concerned (1) HeartWare's efforts to, and success in, remediating the manufacturing, testing, and validation deficiencies identified in the Warning Letter; (2) MVAD's safety profile, including the risk of pump thrombosis; and (3) statements touting MVAD's controller and qPulse algorithm, and the ways in which they enhanced the device's safety profile and commercial viability.

1. Defendants Stated They Were Successfully Remediating the Deficiencies Identified in the Warning Letter

68. As noted above, in the time between HeartWare's receipt of the Warning Letter and the start of the CE Mark trial, Defendants reassured investors that the Company was taking all necessary steps to remediate, and was successfully remediating, the issues the Letter raised, particularly those concerning MVAD. For example, at a June 12, 2014 investor conference, shortly after the Company received the Warning Letter, Godshall told investors that HeartWare was taking the necessary steps to "[m]ake sure that if an FDA reviewer shows up in three months they don't say . . . you had a warning letter and you did the same thing again" with MVAD, and that the Company was working to resolve any problems "before we start any clinical activities [for MVAD] ***so that we are more than squeaky clean***."

69. On HeartWare's July 31, 2014 second quarter earnings call, Godshall stated the Company was taking steps to "***make sure that we are bulletproof*** when we submit [MVAD to regulators to initiate clinical trials] and they don't suggest that there was a looseness, whether it's in test reports or validation work." Godshall specifically highlighted the Company's remediation efforts with respect to documentation and validation "on the electronic side," stating the Company was "***really tight now in terms of open issues that could have resulted in challenges from regulators***."

70. On that same July 31, 2014 conference call, Godshall stated that while MVAD was "so close to being done" as a result of HeartWare's successful remediation efforts, the Company would slightly delay filing its request to European regulators for approval to commence the CE Mark trial. Instead of filing towards the end of summer 2014 as initially planned, the "submission will occur towards the end of this year or early next," in order to allow the Company sufficient

time to ensure that "the sorts of issues that concern the agency were not present in our MVAD program, since the last thing we can afford to do is to make the same mistakes twice."

71. Subsequently, on HeartWare's October 30, 2014 third quarter earnings conference call, Godshall underscored the supposed success the Company was having in remediating the deficiencies the FDA identified in the Warning Letter. Godshall stated, "Most importantly we have made ***significant progress*** in our effort to address the FDA warning letter issues . . . . We have ***upgraded many of our key procedures*** and are already seeing a positive impact from the new approach." On that call Godshall further touted "how ***buttoned up we are being on the MVAD***, given this refresh we've gone through as a result of the warning letter."

72. As the CE Mark trial approached, Godshall continued to communicate to investors that HeartWare was successfully remediating, and had remediated, the issues identified in the Warning Letter, downplaying the scope and magnitude of any remaining fixes. At a November 20, 2014 investor conference, an analyst asked Godshall, "Where are we today with respect to MVAD" in light of the Warning Letter? Godshall responded, "we are finally really there" and are "just tidying up final documentation."

73. In late December 2014, HeartWare submitted its request for regulatory approval to begin the CE Mark trial. Thereafter, Godshall continued to assure investors that the Company was successfully remediating the deficiencies identified in the Warning Letter and that the trial would commence on schedule. For example, at a March 10, 2015 conference, Godshall assured investors, "I see a very little risk to the second quarter start" of the CE Mark trial because the "ability of our team to generate really high-quality regulatory documentation compared to what we did five, six years ago, it's sort of night and day." Likewise, on HeartWare's April 30, 2015 first quarter earnings call, Godshall stated that the Company "continue[s] to make very encouraging strides in

the overhaul of our quality system," and that it was "hard to believe how close we are now" to getting MVAD commercialized.

74. Defendants' statements persuaded analysts that HeartWare was devoting substantial resources to remediating the manufacturing and quality control deficiencies the FDA identified, diligently working to ensure that those deficiencies would not impact MVAD's commercialization, and succeeding in its efforts. In a June 10, 2014 report, William Blair analysts stated, "We continue to have a favorable bias on [HeartWare] given the company's long-term outlook . . . . The company addressed the warning letter that was disclosed last week . . . . [W]e get the sense that the company is being conservative (rightfully so)." In a July 31, 2014 report, Barclays analysts credited Defendants' comments, reporting that HeartWare was taking a "prudent approach around documentation and validation [] given its outstanding warning letter."

75. Even after Defendants announced in July 2014 that they would slightly delay the Company's regulatory filing for the CE Mark trial, analysts credited Defendants' reassuring statements about the effectiveness of the Company's remediation efforts and the promising implications of that success on MVAD's timely and successful commercialization. Barclays analysts noted in an October 30, 2014 report, "Given HTWR has gone through a refresh as it mitigates the warning letter, HTWR feels 'very confident' in its package of data and ability to answer regulators' questions. In the 3Q, HTWR made significant progress in addressing FDA warning letter issues, noting that the majority of its deliverables are on track to be completed by year end. The process includes upgrading procedures, cleaning up documentation, and replacing old product where necessary."

76. In another October 30, 2014 report, Canaccord Genuity analysts stated that they were comforted by HeartWare's assurances its remediation process was essentially complete: "We

thought the update on MVAD was positive . . . . [M]anagement noted ***that the desired adjustments have been made, and they are currently wrapping up documentation for regulatory filing***. If we continue to follow this timeline out, and based off of a similar enrollment speed as seen in Thoratec's HeartMate III study, we continue to believe MVAD approval can come as early as H1:2016."

2. Defendants Emphasized MVAD's Supposedly Favorable Safety Profile, Especially MVAD's Extremely Low Risk of Pump Thrombosis

77. Defendants also made a series of statements asserting that HeartWare's ostensibly robust testing and validation processes showed that MVAD had a highly favorable safety profile, and was less prone to pump thrombosis and other adverse cardiovascular events than its competitors.

78. As discussed above, pump thrombosis is a serious and potentially fatal complication arising from the formation of an obstructive blood clot in the VAD. Pump thrombosis is one of the leading adverse events associated with VADs generally, and is responsible, in part, for stagnant growth in the size of the VAD market as a whole. On August 5, 2015, the FDA issued a Safety Communication "alerting health care providers, patients, and caregivers about serious adverse events associated with LVADS. These adverse events include an increased rate of pump thrombosis (blood clots inside the pump) . . . . Pump thrombosis is a serious complication that can require repeat surgery to replace the pump or can lead to death." As JPMorgan analysts pointed out in an April 17, 2015 report, the VAD market suffered from "increased reluctance among referring physicians to recommend VAD therapy to their patients amid reports of elevated pump thrombosis rates." Godshall himself acknowledged that "stroke and thrombus would be the big two" reasons "that make referring physicians reluctant to refer."

79. Against the backdrop of these concerns, Defendants made numerous reassuring statements to investors that HeartWare's rigorous testing showed that MVAD could not be "thrombosed," had a strong safety profile, and would be a highly successful device. For instance, at a March 3, 2015 investor conference, Godshall claimed, "we frankly can't thrombus, no matter how hard we try in the MVAD." Likewise, at a June 11, 2015 investor conference, Godshall assured the audience, "we have just beat the heck out of this system over time, and we've made so many enhancements to the software we also can't imagine that we're going to find something in the clinic we haven't seen." At that same June 11, 2015 investor conference, Godshall told the audience, "we can't seem to thrombose [MVAD]. Even when we put it in a CircuLite system, where we know we can thrombose things, we still can't thrombose it."

80. As Defendants knew, the market was greatly comforted by Defendants' statements that HeartWare's rigorous testing showed that MVAD could not be "thrombosed" because any indication that the device increased pump thrombosis risk would have a devastating impact on MVAD's commercial viability. Prior to late 2013, clinical trial data showed VADs were associated with a low rate of pump thrombosis relative to other complications, driving patient referrals and fueling investor confidence in the technology. As the November 2013 *NEJM* article discussed above explained, pivotal trials and postmarketing approval studies of MVAD's rival, Thoratec's HeartMate II, from this time period "provide a reference occurrence of thrombosis of 2 to 4%" in the first three months after implantation, which compared favorably with other major morbidities. Moreover, as the *NEJM* article explained, early HeartMate II data showed the device had a median time to thrombosis of 18.6 months after implantation. Because, for many patients, VADs are only a temporary bridge to permanent heart transplantation, time to thrombosis is an important index of safety: the longer the onset of the event, the greater the chance that the patient

will be transitioned to a permanent transplant without incident. Accordingly, doctors and investors viewed the prolonged time to thrombosis in early HeartMate II data favorably. In December 2013, HeartWare published clinical trial data showing similar results for HVAD, with a 2% incidence of pump thrombosis in the first three months after implantation and a median time to thrombosis of approximately 8 months.

81. However, as discussed above, the November 2013 *NEJM* article reported new data that raised concern about more recent HeartMate II implantations, which exhibited an increased incidence of pump thrombosis of 8.4% within just the first three months after implantation. The publication of these data was a blow to Thoratec, and cost the company market share. Wells Fargo analysts, for instance, reported that the Company "lost about 700 basis points (bps) of share to HTWR outside the US . . . . around the thrombosis data with HM2 published in the New England Journal of Medicine (NEJM)," and that Thoratec "will have trouble regaining share in Europe, especially Germany." Most importantly, as discussed above, these data triggered significant anxiety in the medical and investor communities about the overall safety of VADs, leading to a contraction of the market for such devices. Accordingly, the reaction of both the medical community and the market to the *NEJM* article made clear that a device associated with an 8% incidence of pump thrombosis in the first three months after implantation would raise serious concerns in the marketplace.

82. In parallel with HeartWare's development of MVAD, Thoratec also developed the HeartMate III – MVAD's chief rival as a "next generation" pump. As discussed below, in September 2015, Thoratec published HeartMate III trial data showing the device had a 0% pump thrombosis rate in the first 6 months after implantation, putting even more pressure on HeartWare to report a favorable thrombosis profile for MVAD. Indeed, when HeartMate III was later

commercialized, in October 2015, HeartWare's HVAD lost significant market share, putting still more commercial pressure on the Company to report positive news about MVAD.

83. Defendants thus knew that doctors and investors were keenly focused on MVAD's pump thrombosis rate, and were anxious to ensure that MVAD's safety profile was in line with the 2-4% thrombosis rate reported in prior studies that fueled early enthusiasm about the technology's commercial potential, and that it was at least superior to HeartMate II's 8% pump thrombus rate, which caused so much concern about VAD safety.

84. Moreover, investors were particularly concerned about MVAD's propensity to induce pump thrombosis because MVAD's unique design and small size raised the possibility that the incidence of this serious side effect would be particularly high. To accommodate its small size, MVAD's impeller[2] had to spin far faster than larger pumps in order to pump the same amount of blood. Analysts were concerned that MVAD's impeller speed could disrupt normal blood flow or put inordinate stress on the body's arterial walls, making it more likely that clots would form or be dislodged. For instance, Credit Suisse analysts noted, "Concern has been raised by some that because of the high rotational speed of the MVAD impeller (as high as 22K RPM) and the miniaturized size of the device (22 cc displacement for MVAD versus 70 cc for HVAD) that shear stresses will be inordinately high with adverse consequences for the disruption of blood constituents with concomitant increases in the risk for clot generation (due to hemolysis or platelet activation) [*i.e.,* thrombosis] and for bleeding (due to von Willebrand Factor [a protein important to clotting] disruption)."

[2] An impeller is a pump's rotor, responsible for accelerating the blood from the ventricle to the aorta.

85. Accordingly, investors and analysts were comforted by Defendants' assurances that HeartWare's rigorous testing and validation processes showed that MVAD had a highly favorable safety profile with respect to pump thrombosis. In January 2015, for example, Credit Suisse analysts stated, "We came away from our recent conversations with HTWR management impressed with the company's confidence in MVAD's flow capabilities & improvements in the design aimed at reducing thrombus & bleeding risk." Similarly, in a December 7, 2015 report, Sun Trust analysts reported on Defendants' statements that their rigorous testing of MVAD showed the pump had a superior thrombosis profile: "[B]ench experiments indicate that the MVAD is better at morselizing ingested clots (thereby lowering the risk of pump thrombus and ICVA) than was HVAD."

3. Defendants Touted MVAD's qPulse Algorithm and Controller

86. Defendants also emphasized the advantages of two MVAD features: its "next generation" controller, including its supposedly superior alarm, and its qPulse algorithm (which was also housed inside the controller). The controller was a critical computerized component responsible for multiple key functions, including monitoring the pump, providing an interface for the doctor or patient to change the pump's settings, delivering power to the pump itself, and, importantly, controlling alarms that alert patients and doctors to problems with the device. Throughout the Class Period, Godshall stressed that this advanced controller and alarm system were key commercial advantages that would allow MVAD to capture market share.

87. For example, at the March 3, 2015 investor conference mentioned above, Godshall stated that MVAD's controller "has a tremendous number of advantages over other systems." One such advantage, according to Godshall, was the controller's alarm. At a December 10, 2014 investor conference, Godshall stated that the MVAD controller's alarm system contained "[***v***]***ery intuitive alarm conditions so that it will be easy for the patients to know what to do if there is a***

problem." Godshall also emphasized the controller's importance from a commercial perspective. For example, at a May 14, 2015 investor conference, Godshall told the audience that MVAD's "next-generation" controller was "in the mind of many cardiologists, they think this is a bigger deal than the MVAD pump because it is a very user-friendly simple system for the patient, much more sophisticated than what these VAD patients are accustomed to with a touchscreen display."

88. Defendants also promoted MVAD's cutting-edge qPulse algorithm. This software was also housed inside MVAD's controller, and supposedly also increased the device's commercial viability and safety profile. According to HeartWare, qPulse would periodically ramp down the pump's speed, allowing the native heart to function somewhat independently while providing mechanical assistance on an as-needed basis. By maintaining some native heart function, qPulse was supposed to optimize blood flow and reduce the risk of certain adverse heart conditions associated with VADs, such as aortic valve insufficiency. In patients suffering from this condition, the aortic valve does not completely empty all the blood from the ventricle, requiring the ventricle to expand to accommodate additional blood volume and work harder to eject more blood. In a July 20, 2015 press release, HeartWare stated "the MVAD System incorporates a pulsatility algorithm called the qPulse™ Cycle that allows physicians to customize the device for each patient, providing four pulse settings designed to enhance aortic valve function and reduce chronic bleeding events." Indeed, the Company touted qPulse as the "real game breaker" for MVAD, stating that it had "go[ne] a long way to alleviating" some of the adverse safety issues associated with VAD technology.

89. Analysts took note. For instance, BTIG analysts issued a July 20, 2015 report stating, "Potential benefits include pulsatility . . . . [T]he pump will allow multiple pulsatile options, something we have long wondered about the availability of, and this could reduce GI

bleeds and hemorrhagic strokes." Leerink analysts similarly noted that "[t]he MVAD . . . also incorporates a pulsatility algorithm called the qPulse Cycle – a beneficial feature that has the potential to reduce neurological events."

D. In Truth, HeartWare Took No Meaningful Steps to Address the Warning Letter, and the Company's Internal Data Showed Numerous Unresolved Problems with MVAD that Compromised Its Safety and Commercial Viability

90. Unknown to investors, the reality inside HeartWare bore scant relationship to Defendants' public statements. Contrary to Defendants' statements that the Company was successfully remediating the deficiencies in its manufacturing, testing, and validation processes, HeartWare was not taking meaningful steps to remediate, and was not successfully remediating, those deficiencies. As former HeartWare personnel explained, the Company did little to change its testing, validation, and quality control processes after receiving the Warning Letter.

91. Accordingly, contrary to the Company's statements that its newly-remediated testing and validation processes showed that MVAD had a strong safety profile, those processes were inadequate to provide a sound basis for these assertions. Even worse, what little testing and validation HeartWare performed revealed numerous problems with MVAD's software and electronics (including the MVAD controller and its alarms), many of which increased the risk of pump thrombosis, but Defendants ignored them.

92. Former Employee 1 was HeartWare's Director of Program Management from June 2008 through April 2014, and was a member of HeartWare's leadership team, reporting first to the Company's Chief Scientific Officer, Jeff LaRose (who, in turn, reported directly to Godshall) and then to its Senior Vice President for Research, Development, and Quality, Mark Strong (whom Godshall frequently characterized in his public comments to investors as taking a lead role in both HeartWare's remediation efforts and MVAD's development). Former Employee 1 reported that

even before the start of the Class Period, HeartWare was aware of problems with MVAD's software and electronics (particularly the device's controller and alarms), including problems that manifested in the Company's CE Mark trial. Specifically, Former Employee 1 stated that many of the problems that occurred in the CE Mark trial "were known early on and occurred early in the development phase, and I would have expected [them] to be resolved before manufacturing and clinical trials. ***The suction alarm, the algorithms, the qPulse, displays that were blank or showed gibberish – those were problems that dogged the project throughout***." Former Employee 1 further explained that despite these glaring problems with MVAD's design and performance, HeartWare management tried to rush MVAD to marketplace, publicly announcing optimistic timelines they privately knew would not provide adequate opportunity to ensure MVAD was both safe and effective. According to Former Employee 1, management's commitment to unrealistic timelines while simultaneously withholding critical development resources rendered MVAD "hopeless from day one."

93. Former Employee 1 reported that MVAD's controller was plagued by significant deficiencies even before the start of the Class Period due to HeartWare management's decision to break with past practice and task its inexperienced in-house team with designing and developing the controller. Former Employee 1 explained that while HVAD's controller had been designed and built by an outside development firm, HeartWare's senior management had decided to bring the development work for MVAD's controller in-house. However, the electronics staff in Framingham were "not familiar with developing a controller" and "didn't really know what they were doing." HeartWare management was well aware that Company personnel were unfamiliar with controller design, but felt the electronics staff would simply "learn on the job."

94. Given HeartWare's inexperience with controller design, defects and malfunctions soon multiplied and compounded. Former Employee 1 explained that deficiencies in controller software, which would continue to haunt MVAD throughout the Class Period, were particularly pervasive even before the Class Period began. "The software problems were ongoing from the very beginning of the project. That's when I lost confidence that the people in place in Framingham would be able to resolve the issues and develop a controller that worked. The software was never fully and reliably functional, from the day MVAD started to the day I left." According to Former Employee 1, "Nothing really worked right. [There were] improper alarms, improper touch screen performance, gibberish on display screens – just so many alerts and problems and it just wasn't working at all reliably." Indeed, Former Employee 1 explained that there was a "total lack of reliability and robustness in the design of the software to make the product function properly." Former Employee 1 reported, "The electronic control parameters for the pump were not working properly at any time I was there up till I left. There were literally more than 100 hot and critical issues tracked on a daily basis trying to fix them when I left."

95. Former Employee 1 highlighted problems with the controller's alarm system, including the controller's suction alarm, which was "one problem they had from the early stages." As noted above, the suction alarm notifies patients and doctors when the pump is creating an imbalance of pressure in the left ventricle (resulting in suction against the ventricle walls) because of an insufficient blood supply to the ventricle; this can occur where, for instance, the pump removes blood from the ventricle too quickly. Again, an effective suction alarm was particularly indispensable in MVAD because, as Defendants knew and Godshall acknowledged after the Class Period, the pump's "pressure-flow relationship" made it "actually more prone to suction than HVAD." Indeed, "many of the modes that would have an alarm would have some problems."

96. Former Employee 1 also explained that "[o]ne of the biggest issues was heat generation. They designed a compact, ergonomic controller but neglected basic thermodynamic calculations." Former Employee 1 explained that the controller "ran extremely hot – too hot to touch comfortably." Former Employee 1 explained that the controller's propensity to overheat, either while operating or while batteries were charging, was a "big issue" that adversely affected the life of the internal controller batteries and, therefore, the controller itself. Former Employee 1 also explained that MVAD performed poorly in extreme hot or cold temperatures; so, for instance, the controller would "overheat very rapidly" inside a hot car in Arizona. Thus, because MVAD itself generated too much heat, the fact that it did not perform well in high temperature environments only compounded the problem. According to Former Employee 1, these problems "would severely compromise the service potential of the product in the field," and heat degradation "problems were expected." Moreover, because MVAD's batteries were internal to the controller and not easily swappable, "[t]he only thing that can be done" if the batteries degrade "is to swap the controller out, and that can lead to health concerns for patients. A number of patients on cardiac support cannot tolerate a pump stoppage."

97. Former Employee 1 repeatedly expressed concerns about problems with MVAD and the HeartWare team's inexperience to his direct superiors, LaRose and Strong, urging them to work with a medical electronics company to develop the MVAD controller. However, Former Employee 1 stated that Strong ordered personnel to implement "Band-Aid approaches, rather than really resolving the root problems" in order to keep pace with HeartWare's unrealistic and overly aggressive development timelines for MVAD. For example, Former Employee 1 explained that rather than remediate the root cause of the controller's dangerous overheating, management proposed that patients use "a carry bag with more vent holes so it [the controller] has a better

chance of cooling off," and be instructed not to let the controller lay against their skin. Former Employee 1 explained that management's proposed fixes were "Band-Aids to basic, inherent problems that no one wanted to listen to early on. Instead of doing it right, they got so far down the pathway that either you take an 8-month hit [to resolve the issues], or you say this is the best you can do and you make it acceptable."

98. Indeed, Former Employee 1 explained that when MVAD failed performance or safety tests, management would "change the testing or change the spec requirements, so it's acceptable to get it out the door." Former Employee 1 explained, "At one point it was, 'Okay, we'll throw those features out, or accept a display that blinks or isn't bright enough.'"

99. These problems, which continued to affect MVAD through the end of the Class Period, were recorded, tracked, and documented, even before the start of the Class Period. As Former Employee 1 explained, "some of the problems they continue to have were not only on our radar screen later on, but were tracked and [reported] throughout the development process." With respect to the MVAD deficiencies that surfaced in the CE Mark trial, Former Employee 1 stated, "of the problems they've had in the clinical trials, I haven't heard of anything that wasn't on their radar screens early on."

100. Former Employee 1 also reported that despite these deficiencies in MVAD, senior management's "intent was to push [MVAD] out no matter what." Former Employee 1 explained that there were conversations in "every meeting, that the timelines were unrealistic from day one on that project," but there was "no flexibility given from above." When problems arose, the solution offered was for employees to "do whatever it takes." Former Employee 1 explained that "[t]he emphasis from senior management was, 'You're going to meet the timelines; I don't want to hear about any problems." According to Former Employee 1, HeartWare was trying to stay

ahead of its competitor, Thoratec, "trying to push the timeline and downplay engineering issues." Former Employee 1 expressed frustration because "those of us who had some responsibility for timelines would ask for better resources or outside support to improve the likelihood of success, but those requests were ignored or denied."

101. Relatedly, Former Employee 1 stated that HeartWare's publicly announced timelines for MVAD's commercialization were "not based on technical project timelines as presented, but more wishful thinking," were "unrealistic, given the depth of issues in-house," and that "at some point it became very obvious that their communication strategy to the world at large and to shareholders was out of sync with the timelines discussed [internally]." Former Employee 1 explained that Project Managers would provide senior management, including Godshall, with three sets of timelines: a downside case, a base case ("most likely"), and an upside case, which was "really unrealistic" in that it made "a lot of assumptions and expectations that resources would be made available." Former Employee 1 explained that management publicly presented only the "really unrealistic" upside case to shareholders in the Company's quarterly reports. "There's no other way to put it: It was communicated within the company that [management's chosen timelines] were hopeful at best – *maybe* we can have it ready in six months – but I do not think that was the spin [Godshall] was putting on it when he spoke to the investor community." Internally, however, Former Employee 1 explained that "the vast majority of . . . even worst-case schedules [for MVAD development] were not met." Yet, even when the timelines were "slipping throughout the time frame," senior management was "telling the investing community that 'yes, there are problems, but all is or will be resolved and we'll have it out in the next quarter.'" This message was "wishful thinking at best." Former Employee 1 explained that s/he and colleagues would "scratch [their] heads" after listening to Godshall on investor conference calls and wonder,

"How is he coming up with that [timeline]? How can we possibly do that?" Former Employee 1 explained that s/he personally told Godshall that management's timelines were unrealistic and "a number of others let him know that their hopes of getting it out in a certain time frame, the probability of success, timing-wise, was not as high as any of us would like."

102. Importantly, Former Employee 1 also made clear that Godshall knew or should have known about the severe deficiencies affecting MVAD from the very start of the Class Period. Former Employee 1 reported that the numerous problems with MVAD were "widely reported and widely discussed" within HeartWare at weekly MVAD team meetings and at monthly meetings of the MVAD "Project Oversight Board," which Godshall "usually" attended. In addition, as MVAD development ramped up, engineering team meetings were held, on an almost daily basis at times, to address specific technical or regulatory items.

103. Importantly, Former Employee 1 reported that the deficiencies in the MVAD controller's software, including the software controlling the device's alarms, controller display malfunctions, and the controller's propensity to dangerously overheat, among other problems with MVAD, were "definitely" discussed at meetings Godshall personally attended. Moreover, minutes from all meetings were always reported to Godshall, as well as to all of HeartWare's senior management, from Director level and higher, including all vice presidents and senior vice presidents. Finally, Former Employee 1 explained that LaRose and Strong, Godshall's direct reports, were regular attendees at all monthly meetings, weekly team meetings, and daily technical meetings, at which MVAD's deficiencies, including those related by Former Employee 1, were discussed in detail.

104. Former Employee 2 was one of HeartWare's most senior software engineers throughout the Class Period. According to Former Employee 2, HeartWare engineers reported

numerous problems with MVAD's software and electronics through the Company's internal validation tracking system, called "TestTrack," and separately by email, including emails to senior HeartWare management, such as HeartWare's Chief Scientific Officer. Former Employee 2 stated that HeartWare engineers "were not shy about recording that we have problems in the device."

105. The problems documented by HeartWare engineers included serious deficiencies in MVAD's core electronic components. Former Employee 2, like Former Employee 1, explained that, among other things, engineers discovered that MVAD's controller would overheat, adversely affecting the device's internal battery life. According to Former Employee 2, HeartWare engineers expressed concerns to those responsible for MVAD that the controller's propensity to overheat would pose risks for patients enrolled in any clinical trial. Although engineers made "suggestions for mitigating and improving" this defect, HeartWare management made the decision "to go forward anyway" with the MVAD clinical trial timeline.

106. As discussed above, the FDA had specifically admonished HeartWare to remediate its testing and validation processes relating to its device controllers before the start of the Class Period, in both the Form 483 and the Warning Letter. Thus, the Company's failure to mitigate this defect flows directly from HeartWare's overarching failure to meaningfully address the Warning Letter, contrary to Defendants' public claims.

107. Importantly, Former Employee 2 explained that engineers also discovered serious problems with MVAD's software which demonstrated it had not been properly tested, and these defects impacted the pump function in a way that increased the risk of thrombosis, precisely the opposite of what Defendants told investors during the Class Period. For instance, this former employee reported that significant risks were found with the MVAD's "pump pressure algorithm," which was designed to reset the device if internal pressure caused the pump's impeller to move

too far out of place. As Defendants prominently advertised during the Class Period, MVAD's impeller design was unique in that the component was held in place by magnets, rather than fastened to the body of the pump. *See* Figure 3, below. This design was supposed to improve MVAD's safety profile. However, those responsible for MVAD made a decision to reduce the strength of the magnets holding the impeller in place; at the same time, the impeller was redesigned to give the pump greater thrust. Together, Former Employee 2 explained, these design changes "guarantee[d]" the impeller would be forced out of place and would strike the ends of the impeller housing, grinding blood cells "like a mortar and pestle." The impeller's grinding of blood cells described by Former Employee 2 would be expected to cause clots and promote pump thrombosis. According to Former Employee 2, the pump pressure algorithm was "tasked with detecting that we hit the end of the pump, we had a strike, and reducing the pump speed – because HeartWare's testing had shown that below a certain speed you could not get it to strike, so [you want to] reduce the speed and then slowly return it to the former speed." However, Former Employee 2 explained, because the algorithm was "hastily-designed," it failed to properly slow the pump when the impeller was dislocated and ground against the housing. Former Employee 2 explained that a consultant was hired to examine this issue. However, when the consultant discovered that the pump pressure algorithm failed to prevent the impeller from grinding against the pump housing, HeartWare's Chief Scientific Officer, who reported directly to Godshall, told those working on investigating the problem to "cease and desist."

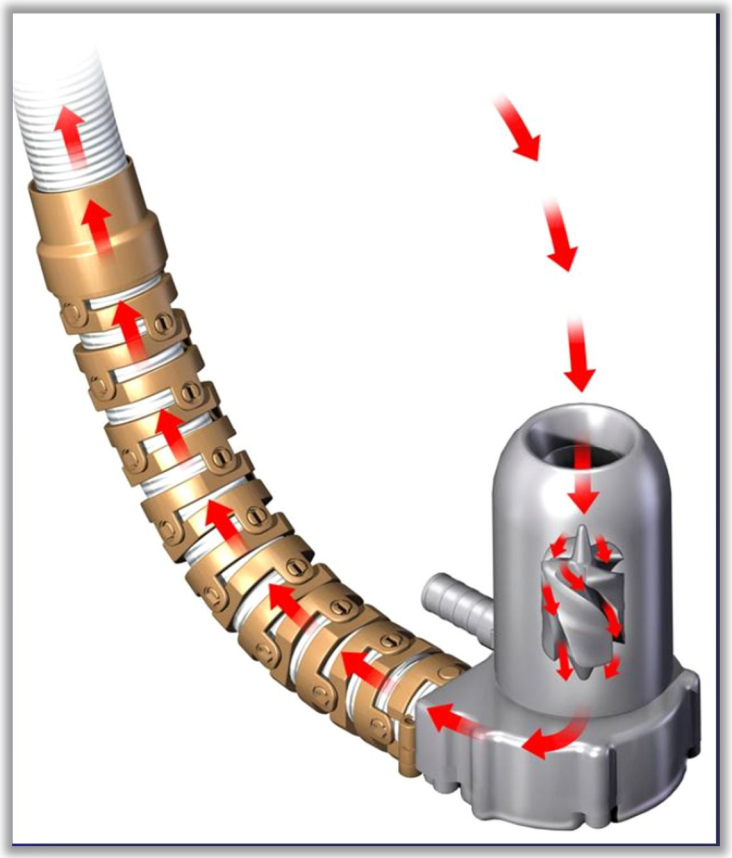

Figure 3. MVAD impeller spinning inside pump housing.

108. Finally, Former Employee 2 explained that because HeartWare's senior management was putting pressure on Company personnel to move MVAD development along as quickly as possible, the software testing for the device was generally inadequate to guarantee it would function properly in a general use setting. Former Employee 2 explained that HeartWare personnel made this concern clear to both HeartWare's Senior Program Manager and to Strong.

109. Contrary to Defendants' reassuring public statements, HeartWare never remediated, or even made a serious attempt to remediate, the deficiencies in testing and validation the FDA had identified in the Warning Letter, including testing and validation of software and electronics. Indeed, Former Employee 2 observed, "Because of undue haste and, at all times, the

focus was only on getting the product out the door and never on – at least with regard to software and electronics – what does it take to establish a method of ensuring we have a safe product."

110. Former Employee 3, the team leader of a Quality Assurance contractor working at HeartWare from October 2014 to July 2015, corroborated Former Employee 2's account. Former Employee 3 explained that HeartWare had "some pretty unusual glitches in [its device] software." For instance, HVAD software would not respond to input/output data in a predictable way. The software "gave a false reading as to the system needing to be replaced; maybe it said the batteries were bad when they weren't," and also outputted false "feedback reports." Yet, despite these "unusual glitches," the Company failed to implement ***any*** "validation from an electrical control perspective" during the Class Period for MVAD. Indeed, Former Employee 3 explained that there was virtually no quality assurance oversight at the Company's Framingham headquarters.

111. Former Employee 3 explained that HeartWare failed to create and maintain reliable "deviation reporting," a reporting system for defects or flaws in the device, again, notwithstanding the Warning Letter's specific instruction to remediate the Company's deficient "corrective and preventative action" procedures. According to Former Employee 3, when changes were made to a device, HeartWare had no system in place to monitor and evaluate those changes, or to mandate retesting. Former Employee 3 also explained that components not specified in original device designs would be improperly substituted for approved elements, and that no system was in place to prevent or document such substitutions. Former Employee 3 noted that the swapped component "could work, but do you want to take that risk?"

112. Former Employee 3 spoke to engineers in Framingham about his concerns that unapproved and untested components had been swapped for approved components, telling them s/he could see that they "did this and this, but no one approved it, so how is it in the inventory?"

Former Employee 3 explained that none of these unapproved swaps were "effectively documented, so Quality can't do a true design history traceability, because certain actions and decisions are made that aren't visible but could be critical." Former Employee 3 noted that the absence of effective documentation evidencing the approval and testing of these components was "absolutely" of regulatory concern.

113. Former Employee 3 further explained that HeartWare had an unusually high number of "field actions," that is, correspondence with patients and doctors to alert them to a problem or defect in their devices. According to Former Employee 3, this was evidence of a systemic failure to "close gaps in procedural controls to ensure a continuously consistent outcome."

114. Moreover, the problems Former Employee 3 raised went unremediated, not because the Company substantively disagreed with Former Employee 3's assessment or analysis, but because the problems would be too expensive or time consuming to fix. "We'd get people saying they didn't want to make changes; it would cost too much to do it." Former Employee 3, echoing Former Employee 1, found that HeartWare was just "putting a lot of Band-Aids on problems."

115. Likewise, Former Employee 4, HeartWare's Program Manager for FDA 483 Warning Letter Remediation for Non-Product Software at the Company's Framingham headquarters from March to August 2014, explained that quality assurance and compliance controls were woefully inadequate at HeartWare. Contrary to Defendants' statements claiming they had adequately addressed the deficiencies in those processes, Former Employee 4 explained that adequate remediation of the problems identified in the Warning Letter "would take years," given the state of HeartWare's internal systems. According to Former Employee 4, HeartWare was "absolutely" noncompliant with cGMP. Former Employee 4 explained that the FDA's

inspection "revealed tremendous gaps between the R&D processes in Framingham versus what was practiced in the manufacturing facility in Miami Lakes," and that these gaps remained when s/he left HeartWare in August 2014.

116. Former Employee 4 noted in particular that HeartWare failed to appropriately monitor and test to ensure that its products were working at each stage of the manufacturing process. Former Employee 4 explained that a Company quality assurance process must ensure that at "each stage of the manufacturing process," the device is "compl[iant] with the parameters" specified by the design engineers, and HeartWare simply "did not have that."

117. Moreover, the Company failed to document required specifications for raw materials and components manufactured by third party contractors, and failed to test and audit those materials to ensure they met design requirements and were suitable for the device's intended use. Former Employee 4 explained that these deficiencies concerned "big issues" that are key to regulatory compliance and "are critical for the long term, or even immediate term of the product." Former Employee 4 also explained that HeartWare had no process in place for auditing the software it used to test and validate its devices.

118. Former Employee 5 was a Validation and Verification Tester at HeartWare from August 2012 to March 2015, and performed validation and verification testing on MVAD, including its controller. Former Employee 5 reported directly to HeartWare's Medical Device Design Verification Engineering Group Lead, and Former Employee 5's work, including problems s/he reported with MVAD, was reviewed by HeartWare's most senior engineering executives, including Jonathan Eagle, the Company's Principal Electronics Engineer, and Sanjeev Pandya, the Director of Research and Development.

119. Former Employee 5, like Former Employees 1 and 2, explained that numerous engineering problems were reported with respect to MVAD (and meticulously recorded in the TestTrack system and reported by email to senior HeartWare management, including Pandya), including the device's controller, but these problems were bypassed in internal validation reporting systems and ignored. Importantly, s/he and other HeartWare personnel observed, and reported, that HeartWare's "suction alarm" on the MVAD controller was defective, corroborating Former Employee 1's account. Former Employee 5 explained that MVAD's suction alarm would not trigger except under the most extreme conditions. According to Former Employee 5, "It literally had to be perfect conditions to get [a] suction" alarm response. Former Employee 5 explained that s/he and other HeartWare personnel "would clamp up and clamp down [on the tube responsible for shuttling blood from the ventricle to the aorta], trying to get the alarm going," but, "[i]t would take forever to get a suction alarm sometimes." According to Former Employee 5, "Eventually we found a way to test so it would work, so [HeartWare's senior engineering executives, including Eagle] said, 'Hey, it's working. Great.' But with the suction alarm, it never felt like it could work." According to Former Employee 5, the suction alarm was "one of the worst alarms" in that it was "difficult to get it working."

120. According to Former Employee 5, rather than remediating the problems that testing revealed, the employees in charge of MVAD "would look at [problems with MVAD] and [say] it's not re-creatable." For example, when HeartWare personnel identified certain problems with the low-flow alarm on MVAD's controller (the controller would trigger false alarms), those responsible for MVAD disregarded those problems, claiming they couldn't recreate the issue, and therefore it was not valid. In fact, Former Employee 5 explained that the low-flow alarm was "an

issue for three years, and nothing had been done about it." According to Former Employee 5, those in charge of MVAD also "put things off to deal with in the future. It didn't seem right."

121. Corroborating Former Employee 1's account, Former Employee 5 also explained that when MVAD failed validation tests, those in charge of MVAD simply changed the requisite specification to be more forgiving in order to get the device to pass the relevant tests. Former Employee 5 explained, "A lot of these issues they were writing up, they were changing the requirements instead of fixing the issues to [meet] the requirement that was already there." For instance, Former Employee 5 explained that initially, MVAD's original specifications required that a battery be no less than 99% charged at "full charge." However, "we couldn't get that, so we changed" the specification to allow a 97% charge to constitute a full charge. Likewise, Former Employee 5 explained that MVAD's original specifications called for the controller alarms to sound at a particular decibel, but Former Employee 5 and his colleagues discovered that the volume of the audio alarm was too low. Instead of fixing the problem, those responsible for MVAD simply changed the specification to allow for the lower alarm decibel.

122. Former Employee 5 further explained that even when validation tests showed there were potential safety issues with the device, those responsible for MVAD ignored those problems. As an example, Former Employee 5 cited a validation test related to the same issue with the life expectancy of MVAD's controller raised by Former Employees 1 and 2. Former Employee 5 explained that engineers found that the controller would overheat and fail when subjected to certain conditions. Former Employee 5 explained that HeartWare engineers had to rerun these tests multiple times to get the controller to pass, until "one time it passed," but even the passing test showed there were "issues." "We were told, 'Hey, those issues are not an issue; just pass it.' It didn't feel right." Moreover, Former Employee 5 explained that the controller's propensity to

overheat adversely affected MVAD's battery life, posing a serious risk to patient safety. Indeed, Former Employee 5 stated that HeartWare's validation team flagged this issue in TestTrack as maximally serious. Yet, even at the time that HeartWare executives declared that direct testing and validation for MVAD had been "successfully" concluded, this issue remained unresolved.

123. Former Employee 5 further stated that MVAD's impeller was insufficiently tested as of the time s/he left HeartWare in March of 2015. Former Employee 5 explained that tests were run on old versions of the impeller, and that the Validation and Verification team had access to the updated version of the impeller for "like a week."

124. Contrary to Defendants' public statements, after the FDA issued the Warning Letter to HeartWare, the Company implemented, at best, cosmetic changes to the manufacturing, testing, and validation processes that were the subject of the Warning Letter. According to Former Employee 5, those processes "didn't change," rather, "[w]e were just doing exactly what we were doing before."

125. Unbeknownst to investors, the consequences of the Company's failure to remedy its deficient manufacturing and quality control processes materialized shortly after the start of the CE Mark trial. Former Employee 6, a HeartWare Clinical Specialist in Hannover, Germany, related a discussion s/he had with an attending physician at one of the first implantations of the MVAD device at the Hannover clinical trial site, which occurred no later than September 8, 2015. Former Employee 6 stated that there were "problems in the operating room" during that implantation. According to Former Employee 6, during that surgery, the surgeons had an extension cable running from the sterilized operating table to the unsterilized controller, but the plug in the controller "didn't sit very well" and "always fell apart." In fact, Former Employee 6 stated, someone supervising the surgery actually "had to tape the connector and controller to each

other" using duct tape – a serious "quality issue" that should never happen in a clinical trial. Importantly, in the Warning Letter it issued to the Company more than a year earlier, the FDA had already cautioned HeartWare to remediate an analogous defect concerning loose "driveline connectors." Former Employee 6 also explained that during several implantation surgeries at the clinical trial site, surgeons encountered problems with the MVAD pump itself – namely, that the device "did not deliver enough flow." As this former employee explained, a medical device responsible for pumping a human heart should never be implanted in a heart failure patient "unless you were 100% sure everything is okay," and "if you're doing a clinical trial, you have to be 500%." Former Employee 6 explained that based on Former Employee 6's 30 years' experience in cardiovascular medicine, Former Employee 6 believed MVAD was not ready for human implantation, but since the trial had already been postponed, "somebody pushed it out."

E. Weeks After Commencing the Long-Awaited CE Mark Trial, Defendants Falsely Assuaged Market Concern Over MVAD's Viability Triggered by the Valtech Transaction

126. By the spring of 2015, the Company was poised to begin the critical CE Mark trial. However, shortly before this trial was set to begin, HeartWare was forced to report negative clinical trial data about its only commercialized product, HVAD. On April 16, 2015, at an international medical conference, HeartWare reported clinical data showing that HVAD increased the risk of stroke significantly more than Thoratec's competing HeartMate II. BTIG analysts, noting that "HVAD's stroke rate looks terrible," worried that the device's safety profile "will be questioned by the FDA" and, as a result, the agency would not approve the device for use in a significant segment of the VAD market. Likewise, Credit Suisse analysts repeatedly pressed the Company for assurances that "those sensitivities" that drove the increased risk of stroke associated with HVAD had been "addressed in MVAD," and therefore, that MVAD's approvability was not

in doubt. Accordingly, the publication of these data put increased pressure on HeartWare to report positive results from its CE Mark trial.

127. With this increased commercial pressure bearing down on HeartWare, the Company proceeded with the CE Mark trial, notwithstanding the numerous serious defects the Company had observed in MVAD and the Company's failure to remediate the deficiencies in its testing and validation processes. On July 20, 2015, the Company announced that it had finally completed its first MVAD implantation in the CE Mark trial. Notably, as set forth above, Defendants had repeatedly represented that their manufacturing, testing, and validation processes would be "bulletproof," "squeaky clean," and "pristine" before the Company initiated the CE Mark trial because Godshall had to personally "sign off" that "we are fully compliant with all the regulations and standards" before any clinical activity could begin. Accordingly, the start of the CE Mark trial signaled to investors that any significant issues identified in the Warning Letter were essentially resolved as they related to MVAD.

128. However, just six weeks after the CE Mark trial began, facts began to emerge that caused the market to question the veracity of Defendants' statements that MVAD was an effective and safe product. Specifically, after the market closed on September 1, 2015, HeartWare stunned investors by announcing a highly dilutive acquisition of a private company, Valtech ("Valtech Transaction"). Notably, Valtech was in a different business than HeartWare. Valtech did not manufacture VADs. Rather, Valtech manufactured a distinct set of medical devices used to treat heart valve disease, including prosthetic devices used in heart valve repair or replacement.

129. Under the terms of the proposed deal, HeartWare shareholders would dilute their existing ownership by approximately 30%-35%, issuing 4.4 million shares to acquire Valtech, with milestone payments that could push the total number of shares issued over 7 million. Notably, as

analysts pointed out, the terms of this deal were highly unusual: in comparable contemporaneous acquisitions in the industry, the acquirer paid with cash rather than stock.

130. The transaction's highly dilutive nature and timing made little economic sense: if Defendants were truly confident in the imminent success of MVAD – supposedly only months from obtaining regulatory marketing approval – it would be irrational to sell a substantial stake in the Company cheaply, before MVAD was launched and the value of the device's success was priced into the stock. Thus, investors questioned whether this "acquisition" was little more than a way for Defendants to hedge HeartWare against MVAD's failure – a failure they knew was looming despite their statements to the contrary – by exchanging a significant equity stake in HeartWare while enthusiasm for MVAD was high and before negative data could emerge and cause the Company's stock to decline.

131. Indeed, analysts and investors immediately recognized that HeartWare's acquisition of Valtech called into question Defendants' prior representations concerning MVAD. Wells Fargo analysts reported that "the most common question" asked by investors they spoke with "the day after" the Valtech Transaction was announced was: if HeartWare was "so confident in MVAD, why dilute your current shareholders by about 30% when your stock could be much higher in 6 to 12 months if MVAD goes smoothly?" This led Wells Fargo to report that "it's unclear to us why HTWR management would dilute its shares by up to 35% if it were bullish on . . . MVAD." These Wells Fargo analysts "point[ed] out this transaction structure deviates from recent acquisitions in the space which have consisted of an upfront cash payment plus a milestone payment on CE marking." Barclays analysts similarly noted, "we think the size of this deal and timing will leave some investors scratching their heads."

132. JPMorgan likewise expressed concern that the Valtech acquisition "represents a dramatic departure from Heartware's history to date," which was "a surprise to investors" and, "combined with the up-front dilution . . . is likely to lead to a negative initial stock reaction." JPMorgan noted that prior to the deal's announcement, the analyst had "viewed the path to value creation at Heartware as a simple one based principally on proving out MVAD's competitiveness." JPMorgan accordingly described the acquisition of Valtech as "a significant change for a company that we had previously expected to deliver rapidly improving profitability over the next 2-3 years."

133. In response to HeartWare's announcement of the Valtech Transaction after the close of trading on September 1, 2015, HeartWare shares precipitously declined by 21%, from $81.81 at the close of trading on September 1 to $64.82 at the close of trading on September 2, on heavy volume of more than 4.3 million shares (compared with an average volume of 270,000 shares traded per day over the three previous months).

134. Nevertheless, Defendants continued to mislead investors about MVAD. On HeartWare's September 1, 2015 investor call, Godshall claimed that the Valtech Transaction did not signal problems with HeartWare's critical MVAD launch, but, ***to the contrary***, was "only possible because of the strength of our core VAD business, as evidenced by several recent milestones." Likewise, Godshall claimed "we are only doing this because of our confidence in our VAD portfolio and pipeline, not because we are concerned about prospects of growth for VADs or concerned about prospects for our portfolio specifically." Godshall stated that "[t]he MVAD System CE Mark clinical trial is now enrolling and, while we won't go into detail, we are quite delighted."

135. Defendants' soothing statements mollified investors and analysts. For instance, on September 2, 2015, Leerink analysts reported, "While this deal is likely to come as a surprise to

most investors from a timing perspective, HTWR emphasized that it is in no way indicative of a lack of confidence in the progression of the company's current LVAD business." Likewise, Barclays analysts stated that while "the size of this deal and timing will leave some investors scratching their heads," "HTWR was insistent that its LVAD portfolio (including MVAD) is doing very well (which we believe) . . . . Given our bullish view of MVAD, bolstered by recent FIM [first-in-man] implants [in the CE Mark trial] and good anecdotal feedback thus far, we remain OW [overweight]."

136. Similarly, one of HeartWare's largest shareholders, Engaged Capital, LLC ("Engaged Capital"), noted in a public letter released on October 5, 2015 that "[o]ften when companies pursue transformational acquisitions it is a reflection of a lack of confidence in the acquirer's core business. However, management has repeatedly asserted post-announcement that their confidence in both the core business and HTWR's next generation device, the MVAD, has never been higher."

137. Unbeknownst to investors however, HeartWare was experiencing manufacturing problems with MVAD's defective controller and, as a result, would shortly announce its intention to suspend the CE Mark trial.

F. On September 9, 2015, HeartWare Announced Problems with MVAD's Controller and Software, But Falsely Reassured Investors that the Device Is Sound

138. Before markets opened on September 9, 2015 – and only a week after Godshall told investors HeartWare was "quite delighted" with MVAD's performance in the CE Mark trial – HeartWare disclosed that it was halting enrollment in the trial because of significant manufacturing problems with MVAD's controller. Notably, the controller was the same device component whose advantages Defendants had touted throughout the Class Period, and the same HVAD component that the Warning Letter had tied to numerous cGMP violations at the Miami Lakes Facility and

reports of serious patient injury or death. On a call with investors, Godshall admitted that the problems with the controller were directly caused by manufacturing deficiencies at the Miami Lakes Facility – the same deficiencies that HeartWare had supposedly remedied. Godshall stated that operators assembling the controller "were putting too much stress on some of the circuit boards, for one circuit board in particular" and that "we're seeing some components on the board that are not as – on as securely as they're supposed to be." In other words, the controllers fell apart because they were manufactured improperly. Godshall told investors that the Company had developed a manufacturing solution to the problem, but that it would take eight to ten weeks to build and test the solution, during which time no additional patients would be enrolled beyond the 11 who had already received implants.

139. On that same September 9, 2015 call, HeartWare disclosed yet another problem with MVAD's controller, this one caused by the Company's deficient software validation: a software defect was causing the controller's screen to go blank. HeartWare would now be required to write new computer code to fix the problem, a remedial action that qualified as a "design change," necessitating further regulatory approval, and adding to the mounting risk that HeartWare would fall behind on its MVAD commercialization timeline. As alleged above, MVAD's controller software had caused display malfunctions from before the start of the Class Period, yet this defect, unbeknownst to investors, was never remediated.

140. However, Defendants continued to make a series of reassuring statements that persuaded investors that additional problems and delays were unlikely, and neutralized any decline in HeartWare's share price. For instance, on HeartWare's September 9, 2015 investor call, Godshall stated, "we've been working through a warning letter, making phenomenal progress on that and as we uncover opportunities to improve our quality, we implement them." In fact,

Godshall claimed that the strength of the Company's remediated testing and quality control processes had allowed it to identify the controller issues the Company disclosed in the first instance: "we're now luckily at a point where we have the bench strength that you can find these things and fix these things quickly . . . . And so we now find things and fix things."

141. Godshall also emphasized that the issues disclosed were unrelated to the MVAD pump's performance or safety, which Godshall continued to claim the Company's rigorous testing had thoroughly vetted: "on the pump side, we tested it so much that we really weren't worried and I think it suggests we have good reason for not having [been] worried." Indeed, Godshall stated that apart from the minor issues disclosed, "[t]he controller is working great." Accordingly, Godshall continued to tout the MVAD's supposedly strong safety profile, stating, "my expectation is that this is going to be a device that has dramatically lower adverse events than certainly what we've seen historically as a field, not just as a company." Similarly, Godshall claimed that progress in the CE Mark trial was promising, stating, "we are thrilled with how the device is performing," and "so far[,] so good" in the trial.

142. Finally, Godshall also continued to reassure investors that the Valtech Transaction did not signal anything negative about the MVAD: "there was a misperception that concerns about MVAD drove Valtech -- couldn't be further from the truth. Confidence in MVAD gave us confidence to create a broader heart failure company around the MVAD platform."

143. Analysts were comforted by Defendants' statements and, accordingly, made no adjustments to their HeartWare models. For instance, Piper Jaffray analysts issued a September 9, 2015 report, in which they stated,

> While the delay and its timing are both less than ideal, the news that the issue was associated with the controller vs. the MVAD pump itself (***along with the update that the 11 patients implanted in the CE Mark trial to date are doing well***) ***significantly reduces the risk associated with the pause in trial enrollment in our***

> ***view***. Management again emphasized that the recent Valtech deal is not a hedge against MVAD and stated that physician excitement and demand around MVAD remain robust.

144. Likewise, Canaccord analysts stated that while, "management today announced a voluntary pause of trial enrollment in their ongoing MVAD CE Mark clinical trial," "[w]e would highlight that these issues pertain solely to the controller and do not impact pump performance, a critical differentiation, in our view." Similarly, William Blair analysts reported, "We spoke with the company which stated that the issues have not been seen in study devices and do not affect pump performance; therefore, we should not see any long-term impact to MVAD adoption." Finally, Credit Suisse analysts stated that notwithstanding the "execution risk" HeartWare's disclosures revealed, they continued to "see this issue as very manageable."

G. Unbeknownst To Investors, Patients In the CE Mark Trial Suffered Pump Thrombosis at Extremely High Rates and Unusually Rapidly After Implantation

145. Just after the Company's September 9, 2015 announcement of a pause in the CE Mark trial, HeartWare was confronted with deeply concerning data indicating that MVAD posed a severe risk of pump thrombosis. Specifically, in the first 11 patients implanted with MVAD, there were three incidents of pump thrombosis. Significantly, these dangerous adverse events had occurred at a rate of more than 27%, which was vastly in excess of prior reported incidence rates.

146. As noted above, pivotal trials and postmarketing approval studies of MVAD's rival, Thoratec's HeartMate II, "provide a reference occurrence of thrombosis of 2 to 4%" in the first three months after implantation, while HeartWare's trial data similarly showed HVAD was associated with a 2% rate in that time period. The ***27%*** incidence of pump thrombosis observed in the CE Mark trial was therefore between 7 and 13 times the adverse event rate associated with these prior trials and studies of HeartMate II and HVAD. Further, the 27% rate of pump thrombosis observed in the CE Mark trial represented more than a three-fold increase over

HeartMate's alarming 8% incidence of pump thrombosis reported in the November 2013 *NEJM* article – a finding that was responsible for causing serious concern amongst doctors and investors about the safety of VADs. In other words, in the CE Mark trial, HeartWare had observed the same early-occurring thromboses at more than three times the rate that pushed independent clinicians to publicly sound a warning in the most prominent medical journal in the world (and that cost Thoratec significant market share). These developments seriously called into question MVAD's safety and commercial viability.

147. While HeartWare was in possession of this information, Godshall met with analysts and reassured them that all was well with MVAD, and that the Company would disclose any significant issues that had arisen in the first 11 patients. On September 28, 2015 Leerink analysts reported that they had "hosted a site visit to HTWR with CEO Doug Godshall, CFO Peter McAree, and VP of Investor Relations Chris Taylor. Overall the tone of the meeting was positive and left us feeling more comfortable with HTWR's competitive positioning in light of yet another several month delay in its next-gen MVAD."

148. The analysts further reported that the 8 to 10 week pause in the trial announced on September 9, 2015 gave HeartWare a "somewhat unique opportunity to review the early data in these patients – in essence a 'confirmatory' safety study that could also aid in its discussion with the FDA on the start of a U.S. pivotal trial." The analysts reported that, "In the meantime, HTWR noted that it would disclose any major issues should they occur in the 11 existing MVAD patients."

149. Nevertheless, rather than disclosing the disturbingly high incidence and unusually rapid onset of pump thrombosis experienced by the first 11 patients, Defendants did the opposite and withheld it. The Leerink analysts reported that a "key takeaway" from their meeting with Godshall and HeartWare's other senior executives was that "there is no negative news regarding

MVAD – now implanted in 11 patients in Europe – that would prompt any sort of design change." Indeed, far from disclosing this significant negative news, Defendants continued to withhold it from investors until their hand was forced by market rumors that began swirling on October 12, as set forth below.

150. Defendants were withholding this material negative news at a time when disclosure would have been particularly harmful to the Company – namely, a time when HeartWare's competitor, Thoratec, was experiencing significant success with its next generation VAD, HeartMate III. As mentioned above, on September 27, 2015, Thoratec published HeartMate III trial data showing that device had a 0% pump thrombosis rate throughout the six month duration of the study. Thoratec reported that its trial data showed "very low adverse event rates highlighted by zero pump thrombosis events." The data showed that HeartMate III was associated with a remarkably low incidence of the very same types of adverse events HeartWare claimed MVAD would reduce, such as pump thrombosis. Thoratec reported that "[t]here were no instances of pump thrombosis, hemolysis, or device malfunction during the six month follow-up period." In other words, at the same time Defendants were confronted with alarming safety data for MVAD, HeartMate III had pushed the benchmark for commercial competitiveness in terms of critically important pump thrombosis even higher.

H. On October 12, 2015, In Response to Market Rumors that MVAD Patients in the CE Mark Trial Experienced Adverse Events, Defendants Falsely Assured Investors that the Events Were "Typical"

151. On October 12, 2015, market rumors began to emerge that the Company may have observed a cluster of adverse events in the CE Mark trial, and that something could be fundamentally wrong with the MVAD pump. For instance, Wells Fargo analysts reported rumors that MVAD was encountering difficulties in the CE Mark trial. The analysts stated, "[w]e recently heard that there may be issues with the pump itself. When we spoke with the company about this,

the company stated that it has not changed its position that it plans to re-start the trial in November. Any new issues with MVAD would make us incrementally concerned about HTWR given the importance of MVAD to the company and the stock." HeartWare's stock reacted negatively to the publication of these rumors. In an article published during the October 12, 2015 trading session, *Bloomberg* reported, "HeartWare down as much as 15% to lowest intraday since March 24 on volume 80% 3-month avg. after Wells Fargo analyst Lawrence Biegelsen wrote note saying he recently heard there may be issues with MVAD pump."

152. That same day, in response to the publication of these rumors, HeartWare published an announcement on the "Investor Relations" section of its website stating that, after the Company paused the CE Mark trial on September 9, it began investigating "causes of reported adverse events in certain clinical trial patients." The Company further disclosed that given the ongoing investigation into those adverse events, "HeartWare may not re-initiate enrollment in the MVAD clinical trial in November as it previously expected." The next day, on October 13, Defendants published this announcement in a "Regulation FD disclosure," filed to address an issuer's selective disclosure of material information, on Form 8-K. In these disclosures, however, HeartWare failed to disclose the number or nature of the adverse events observed.

153. Notably, as Canaccord analysts noted, "HTWR felt compelled to comment about the adverse events in its MVAD trial" because of the decline of HeartWare's share price in response to the rumors published by analysts. As Godshall himself stated on a November call with investors, "whether we would've ever talked about [the adverse events disclosed on October 12, 2015] publicly or just gone on and run the trial, had rumors not been spreading about the trial, I'll never know."

154. Analysts were troubled by Defendants' October 12, 2015 disclosures. In an October 19, 2015 report, for instance, JPMorgan analysts remarked that "the adverse events that have occurred are concerning." Similarly, Canaccord analysts noted, "Obviously the MVAD CE Mark trial delay – and concern about the viability of the platform in light of adverse events in the trial in Europe – is top-of-mind for investors. We now expect MVAD developments to delay a US pivotal trial until mid-2016." BTIG analysts likewise concluded that MVAD "is now a show-me story."

155. Analysts also noted that the opacity of Defendants' disclosures – specifically, the absence of confirmation of either the nature or number of the adverse events – prevented them from independently assessing the severity of the adverse events and the extent to which they impacted MVAD's commercial viability. Credit Suisse analysts stated in an October 13, 2015 report, for example, "HTWR has not provided any color on the expected duration of the pause other than to note that the adverse events are typical of ventricular assist device or (VAD) trials & that it 'took similar actions' during its EU HVAD trial. Given that VAD trial adverse events can range from minor infections to disabling stroke & death this disclosure does little to help us frame the potential risk." Barclays analysts noted, "HTWR would not provide any more specifics on the adverse events or how other patients are doing, seeing this disclosure path as a slippery slope." In an October 13, 2015 report, Piper Jaffray analysts similarly stated that in "address[ing] recent speculation of adverse events" in the CE Mark trial, HeartWare's disclosures failed to "defin[e] the nature of the AEs (or the number)."

156. In response to the October 12, 2015 disclosures, HeartWare shares plunged nearly 30%, from $50.07 per share on October 9, 2015 (the last trading day before October 12) to close

at $35.21 per share on October 13, 2015, on heavy volume of approximately 1.6 million shares traded on October 12 and 6.1 million shares traded on October 13.

157. In order to quell the negative rumors concerning MVAD and the CE Mark trial and spin the story in a way that would soothe investors, Defendants continued to issue false and misleading reassurances to the marketplace that prevented HeartWare's stock from assimilating the complete truth about HeartWare's deficient manufacturing, testing, and validation processes, the progress of the CE Mark trial, and MVAD's safety profile.

158. *First*, in their October 12, 2015 disclosure and in subsequent statements, Defendants falsely stated that "[t]he events being analyzed are typical of those seen in other clinical trials for ventricular assist devices." Moreover, Defendants continued to state that the CE Mark trial was yielding positive and encouraging results. For instance, on HeartWare's October 29, 2015 third quarter earnings call, Godshall claimed "our initial experience [in the CE Mark trial] has us more convinced than ever that the MVAD will be extremely successful in the clinic and ultimately in the marketplace."

159. Defendants' soothing statements that the adverse events observed in the CE Mark trial were "typical" and that the Company's "initial experience" in the trial indicated MVAD would be "extremely successful" were false and misleading. As explained above, unknown to investors at the time, HeartWare had observed 3 pump thromboses – serious events that are of particular concern to investors – in 11 patients, and these thromboses occurred in an unusually rapid time frame, *i.e.* within, at most, three months after implantation. [3] The ***27%*** incidence of pump thrombosis was between 7 and 13 times the adverse event rate associated with prior trials and

[3] As discussed above, the first implantation in the CE Mark trial took place in mid-July 2015, with additional implantations occurring thereafter. Accordingly, these events occurred no more than three months after implantation.

studies of HeartMate II and HVAD, and a three-fold increase over HeartMate's alarming 8% incidence of pump thrombosis reported in the November 2013 *NEJM* article. Additionally, the incidents of thrombosis observed in the CE Mark trial occurred many times more rapidly than events in HeartMate II, which data showed had a median time to thrombosis of 18.6 months after implantation, and more rapidly than events in HVAD, which data showed had a median time to thrombosis of approximately 8 months after implantation.

160. Moreover, the thrombus signal Defendants observed was far in excess of the 0% thrombus rate associated with HeartMate III – MVAD's chief rival in the "next generation" VAD market and direct commercial competitor.

161. Thus, the pump thromboses observed in the CE Mark trial were simply not "typical" occurrences, and Defendant Godshall's statements that he was "more convinced than ever that the MVAD will be extremely successful in the clinic and ultimately in the marketplace" lacked a reasonable basis. However, because Defendants failed to disclose any details concerning the adverse events they were investigating, investors were in no position to assess the truthfulness of these claims.

162. *Second*, Godshall continued to reassure investors that HeartWare had made great progress in remediating its manufacturing, testing, and validation deficiencies, and this remediation showed that MVAD's design was sound. For instance, on HeartWare's October 29, 2015 earnings call, Godshall stated, "our MVAD focus is now on manufacturing tolerances. We are encouraged by our initial findings from the clinical and technical review and presently we do not see any evidence that a redesign will be warranted." Godshall further reassured investors, "the MVAD status may give the impression that execution is challenged at HeartWare, but this couldn't be further from the truth. Between MVAD, warning letter and HVAD enhancement, our internal

execution has never been stronger." Similarly, at a November 11, 2015 investor conference, Godshall stated that "we don't see any evidence that any design change to the pump is warranted." Likewise, at a December 1, 2015 investor conference, Godshall claimed, "we have tremendous control over our processes," "we measure everything now," and that given the now-rigorous "incremental testing that we've done to give ourselves comfort," HeartWare "remain[ed] very optimistic that the core design is actually quite excellent."

163. These soothing statements were likewise false and misleading. Again, contrary to their claims, Defendants failed to adequately remediate the manufacturing, testing, and validation deficiencies that the FDA identified in the Warning Letter. As such, Defendants' assurances that their supposedly reinvigorated testing and validation processes showed that MVAD's design was sound were also misleading because, unbeknownst to investors (but as Defendants knew or should have known), those deficient processes were incapable of providing such comfort. Moreover, contrary to the assertion that HeartWare was "encouraged by our initial findings from the clinical and technical review" and "do not see any evidence that a redesign will be warranted," as noted above, HeartWare's internal data showed that MVAD had numerous deficiencies in its software and electronics, and that patients experienced an unusually high incidence of pump thrombosis occurring unusually quickly after implantation, which indicated that the device was fundamentally defective.

164. *Third*, Defendants continued to specifically tout the strength and promise of HeartWare's inadequately tested qPulse algorithm. For instance, at a November 11, 2015 investor conference, Godshall stated, "MVAD will also have a pulsatility algorithm . . . which should have a benefit in terms of reduced aortic insufficiency." And again on November 19, 2015, Godshall stated, "QPulse should further improve aortic valve function."

165. Again, Defendants' soothing statements were false and misleading. It was misleading to tout MVAD's safety profile (and qPulse's contribution to that safety profile) at the same time that an unusually large number of MVAD patients were experiencing pump thrombosis unusually early in the CE Mark trial. At minimum, these statements lacked a reasonable basis given what Defendants knew at the time.

166. Analysts, however, were comforted by Defendants' statements. JPMorgan analysts, for example, reported, "While the adverse events that have occurred are concerning, the majority of the pumps implanted to date appear to be functioning well. As a result, we believe that additional problems would need to surface to convince management that an actual design issue exists." Canaccord Genuity analysts reported on October 13, 2015 that HeartWare "management is confident that there is no need [to] make any significant design changes to the MVAD pump," and any delay was due only "to their desire to be comprehensive and answering all outstanding issues on the controller, and any questions from investigators on the possible adverse events . . . . [M]anagement still believes that it is possible that the trial can restart in November." Piper Jaffray likewise reported on October 13 that "Godshall . . . expressed confidence in the MVAD pump design" and stressed that "fundamental design changes" were not necessary.

167. Leerink analysts echoed this bullish view in an October 30, 2015 report: "HTWR management did provide an MVAD update on the call, noting that their own internal investigation has led them to believe that tightening manufacturing specifications could be enough to improve pump performance and prompt a trial restart. CEO Doug Godshall noted that, as of right now, he does not believe any design change or tweak is warranted . . . . We reiterate our [Outperform] rating given our view that the shares now adequately reflect the clinical risk associated with HTWR's next-gen MVAD."

I. On January 11, Defendants Announced that Nearly Half of the CE Mark Patients Experienced Serious Adverse Cardiovascular Events Due To Pump Thrombosis and that MVAD Likely Required a Redesign

168. At a January 11, 2016, investor conference, Godshall shocked investors by announcing that contrary to his prior statements that MVAD could not be "thrombosed," nearly ***half*** of the patients enrolled in the CE Mark trial experienced pump thrombosis, an incidence that was dramatically worse than the rate reported by MVAD's chief competitors, as discussed above.

169. Godshall further explained that, contrary to his prior statements that the qPulse algorithm enhanced MVAD's safety, the algorithm created particularly unusual and dangerous conditions that caused pump thromboses. Among other things, the qPulse algorithm would speed up the pump, causing what is known as a "suction event," *i.e.*, insufficient blood supply to the left ventricle causing an imbalance of pressure in the ventricle and suction against the ventricle walls, in this case, a result of the pump delivering blood to the aorta far too quickly. While suction events may occur in competing VADs, MVAD's qPulse caused unusually long suction events. According to Godshall, qPulse would cause patients to stay "***in a sustained suction mode for weeks or months***."

170. Moreover, while MVAD was equipped with a "suction alarm," that alarm was defective, as Former Employees 1 and 5 explained HeartWare personnel had observed when testing MVAD before the start of the CE Mark trial and, indeed, before the start of the Class Period. As Godshall admitted, MVAD's supposedly superior alarm failed to alert patients to suction events, even when they occurred for prolonged periods of time. The irregular flow caused by the suction events, coupled with the defective alarm, contributed to an unusually high incidence of pump thrombosis in the CE Mark trial.

171. HeartWare told investors that it would indefinitely suspend the CE Mark trial while seeking to repair both its qPulse algorithm and its "suction alarm detection system," efforts the

Company expected would take at least "several months." The Company additionally disclosed that given the extent of the remediation required, the Company might not be able to resume the CE Mark trial it had already initiated, but would have to restart the clinical trial process from the very beginning.

172. Defendants' disclosures revealed to investors that HeartWare had not remediated its manufacturing, validation, and testing processes, and that Defendants' repeated statements that MVAD was a promising device with an excellent safety profile and, in particular, a low risk of pump thrombosis, were untrue. Given the fact that pump thrombosis was an adverse event that received particular attention and concern from doctors and investors, and that Defendants had singled out as the subject of rigorous pre-trial testing, MVAD's propensity to so readily inflict that type of injury in the CE Mark trial demonstrated just how deficient HeartWare's testing and validation process really was.

173. Analysts were shocked by HeartWare's disclosures and immediately revised their estimates of the Company's performance downwards. For instance, JPMorgan analysts issued a January 12, 2016 report downgrading HeartWare to neutral because "Mounting MVAD Uncertainty [Is] Too Much to Stomach." These analysts noted,

> [N]early half of the 11 patients implanted with MVAD thus far have now suffered a serious adverse outcome. This significantly increases the odds that a redesign of the pump and/or a protracted regulatory delay may be required to bring MVAD to market, in our view, while raising doubts about its ultimate competitiveness. Given the importance of MVAD to our long-term thesis on Heartware and what we see as a lack of potential near-term catalysts, ***we can no longer recommend the stock***.

174. Similarly, Barclays analysts "stripped most of MVAD out of the valuation for the time being." Piper Jaffray analysts likewise noted that HeartWare's disclosures impugned MVAD's commercial viability, significantly impairing the value of HeartWare stock.

> With 5 of 11 MVAD patients now having adverse events we believe a restart of the existing trial is unlikely and HTWR must either look to start a new trial with potential software modifications or pursue a redesign of the MVAD pump . . . . The story for us is the continued uncertainty on the viability of MVAD, and until we have clarity around the timeline to get back in the clinic or whether or not the company needs to start from scratch, we remain on the sidelines.

175. In response to the January 11, 2016 disclosures, HeartWare shares plunged more than 35% in a single day. HeartWare shares fell from $40.84 per share on January 11, 2016 to close at $26.50 per share on January 12, 2016, on heavy volume of more than 7 million shares.

176. In all, disclosures of the true facts concerning HeartWare's failure to remediate its manufacturing, testing, and validation processes, MVAD's performance in the CE Mark trials, and MVAD's safety risks caused massive losses to investors, with HeartWare shares falling nearly 68%, from $81.81 per share at the close of trading on September 1, 2015, to $26.50 per share at the close of trading on January 12, 2016.

J. Post-Class Period Developments

177. On January 28, 2016, HeartWare announced the Company's intention to abandon the Valtech acquisition. This announcement came after months of strident shareholder opposition to the deal. In particular, Engaged Capital, one of HeartWare's largest investors, had opposed the transaction almost immediately after it was announced, and had threatened, in an October 5, 2015 letter to HeartWare's board of directors, to launch a proxy fight seeking to replace members of the board if HeartWare persisted in seeking to consummate the Valtech Transaction. Engaged Capital demonstrated its willingness to make good on that threat by nominating a slate of insurgent directors on December 30, 2015.

178. In an effort to avoid a proxy battle seeking to replace members of HeartWare's board of directors, the Company backed out of the Valtech Transaction. On the same day HeartWare announced it was scuttling the deal, January 28, 2016, HeartWare also announced that

it had entered into a "Cooperation Agreement" with Engaged Capital, pursuant to which the two parties would jointly select "an additional independent director," while Engaged Capital would "withdraw its previously nominated slate of directors for election at the annual meeting" and, in light of the termination of the Valtech acquisition, would forego its proxy battle opposing the deal.

179. On May 4, 2016, HeartWare held its first quarter 2016 earnings call. On that earnings call, Godshall told investors that HeartWare would not resume the paused CE Mark trial, but would instead begin a new trial, given the dismal safety results observed in the initial CE Mark trial and the Company's need to modify MVAD. Godshall stated, "I think the most prudent path is to start a new [trial]. You've got enough events in that cohort that you'd rather not burden your final study report with several events and try to explain them away." As Godshall explained, restarting the CE Mark trial would meaningfully delay the device's market launch, as the remediated device would need to go through significant additional testing. However, Godshall could not provide a concrete timetable for restarting the trial.

180. On June 27, 2016, HeartWare announced that Medtronic plc, a medical technology manufacturer, had agreed to acquire the Company for $58 per share. While the purchase price represents a premium to HeartWare stock's closing price of $29.98 just before the deal was announced, it represents a 39% discount from HeartWare stock's intra-Class Period high of $94.47.

VI. ADDITIONAL SCIENTER ALLEGATIONS

181. Numerous allegations set forth above and summarized below give rise to the strong inference that Defendants at least recklessly misled investors about their efforts to remediate the manufacturing, testing, and validation deficiencies identified in the Warning Letter, their success in remediating those deficiencies, the progress of the CE Mark trial, and the safety profile and commercial viability of MVAD. These allegations include the following:

182. First, throughout the Class Period, Godshall assured investors that HeartWare management was deeply focused on, and actively managing, the Company's efforts to address the Warning Letter. In particular, Godshall emphasized his own role in personally overseeing the Company's remediation process. As alleged above, Godshall told investors that HeartWare's "new Number 1 priority" was to "address those concerns of the FDA," and that "from the moment [the Warning Letter] arrived, it became our highest priority. We immediately began to shift energy, attention, and resources to address the observations." Similarly, Godshall told investors, for example, that in light of the Warning Letter, "We want to make sure that our clinical and technical teams are completely obsessed with MVAD right now," and that HeartWare was "now narrowing our focus to specific areas within our manufacturing process." Godshall also explained to investors that he was personally responsible "sign[ing] off" that MVAD was compliant with all pertinent regulations before any clinical trial activity could begin. Yet, while Godshall was making these repeated assurances, he issued a host of false statements, in which he grossly mischaracterized HeartWare's success in remediating the deficiencies identified by the Warning Letter. Either Godshall possessed the detailed personal knowledge concerning HeartWare's purported remediation efforts he claimed to have, in which case he knew that those efforts were profoundly inadequate, or Godshall lacked the knowledge he claimed to have, in which case his repeated statements on the subject were severely reckless.

183. Second, the highly dilutive Valtech Transaction could only have been arranged with the approval of HeartWare's senior management, including Godshall, and this transaction would have made little economic sense had Defendants truly been unaware of meaningful problems with MVAD and confident in MVAD's success, as they publicly claimed to be. As alleged above, under the terms of the Valtech Transaction, HeartWare would issue 4.4 million shares to acquire

Valtech, with milestone payments that could push the total number of shares issued over 7 million. Thus, although HeartWare's senior management, including Godshall, claimed to be highly confident that MVAD would successfully complete its round of marketing approval trials and enjoy a near-term launch that would cause HeartWare stock to significantly appreciate, they proposed ***selling*** approximately 35% of the Company just months before that launch took place. Moreover, as analysts pointed out, the terms of the Valtech Transaction were unusual: in contemporaneous comparable acquisitions, the consideration paid by the acquirer consisted entirely of cash. Had Defendants believed that MVAD was going to be successful (and therefore HeartWare stock would enjoy considerable near-term upside), as they certainly led investors to believe, comparable deal precedent makes clear that they could have paid for Valtech in cash. As analysts openly wondered, if HeartWare was "so confident in MVAD, why dilute your current shareholders by about 30% when your stock could be much higher in 6 to 12 months if MVAD goes smoothly?" The deal's timing was additionally suspicious, as it was announced ***just days*** before HeartWare disclosed the Company would suspend the CE Mark trial as a result of manufacturing problems with MVAD and ***just weeks*** before the Company was forced to admit that the trial would be further delayed as a result of adverse events experienced by enrolled patients. The timing and structure of the deal raises a strong inference, that contrary to their public statements to investors, Defendants were seriously concerned about MVAD's commercial viability, and that the deal was an attempt to unload a significant equity stake in the Company shortly before negative facts emerged causing HeartWare stock to decline.

184. Third, the egregiousness of the deficiencies in HeartWare's core manufacturing, testing, and validation processes support an inference of scienter. As numerous former HeartWare employees confirmed, those deficiencies were blatant and pervasive, and could not have

reasonably escaped management's attention – especially given Defendants' purported focus on these very areas – had Defendants undertaken the testing and review they claimed they had. As alleged above, while Defendants made repeated statements touting HeartWare's successful remediation of its software and electronics validation and testing processes in particular, former employees have explained the Company lacked ***any*** "validation [of the device] from an electrical control perspective" during the Class Period. Indeed, HeartWare's own internal validation tracking system, TestTrack, showed that HeartWare engineers reported numerous problems with MVAD's software and electronics, including problems with the controller's alarm system, that were never remediated, but instead ignored or circumvented. HeartWare's failure to address the Warning Letter was not formal or technical – it was manifest. As former employees confirmed, HeartWare employees "were just doing exactly what [they] were doing before." Yet at the same time that HeartWare's quality assurance and manufacturing processes were in such bad repair that it "would [have] take[n] years" to actually remediate them, Defendants repeatedly touted the strength of those very processes.

185. Fourth, the character of the dangerous defects in MVAD further supports an inference of scienter. These defects concerned MVAD's qPulse algorithm and controller, elements of MVAD that Defendants repeatedly touted as key, and concerned MVAD's propensity to cause pump thrombosis, the aspect of the device's safety profile that was among the most critical to its commercial viability. Again, Defendants repeatedly advertised MVAD's qPulse and controller as MVAD's "real game breaker" and "next-generation." And knowing investors were deeply focused on the pump thrombosis risk associated with MVAD, Defendants made numerous statements claiming pump thrombosis was an adverse event for which MVAD had been especially vigorously tested and that HeartWare personnel could not "thrombose" the device no matter how hard they

tried. That these defects concerned aspects of MVAD that Defendants repeatedly and prominently highlighted, and knew were the subject of investor attention and concern, supports an inference of recklessness at a minimum. Moreover, the defects that went unremediated were extreme in kind and degree. For example, as alleged above, MVAD's qPulse algorithm caused patients to experience unusually dangerous "suction events" leading to pump thrombosis. Whereas a VAD patient might normally experience a suction event for minutes before the device's alarm is triggered, MVAD's qPulse caused the pump to ramp up speed in such an extreme and uncontrolled way that CE Mark patients experienced prolonged suction events for ***weeks and months*** without triggering the device's clearly defective alarm. HeartWare's failure to remediate MVAD's suction alarm is particularly egregious in light of the fact that its leadership, including Godshall, knew the device was "more prone" to suction events than HVAD. As a result of qPulse's defects, ***half*** the patients enrolled in the CE Mark trial experienced dangerous pump thromboses, many of those events occurring unusually early after implantation of the device. Other problems with MVAD's controller were likewise so glaring that they were apparent from the start of the CE Mark trial. For instance, as discussed above, in one of the trial's first implantations, surgeons "had to tape the connector and controller to each other" to prevent the MVAD from falling apart. The magnitude of the defects that HeartWare failed to remediate prior to implantation is powerful evidence of the extraordinary deficiencies in the Company's quality control and manufacturing processes, and further supports an inference that Defendants' repeated statements about the strength of those processes and MVAD's safety were made with either a deliberate attempt to deceive or in reckless disregard of obvious facts.

186. Fifth, that Defendants' misstatements concerned the most significant events relating to HeartWare's most material product supports an inference of scienter, particularly as

HeartWare was a small company with little else to distract management or divide its attention. As alleged above, HeartWare markets only a single product and, for most of the Class Period, had no more than two others in development. Notably, MVAD was clearly the subject of outsized management and investor attention throughout the Class Period. As alleged above, management characterized MVAD as "the biggest deal in the VAD space probably for the next three or four years," as "a major driver of stronger growth in [] 2016, 2017, 2018[, and] beyond," and as a key reason Defendants were "most optimistic about the longer-term prospects for HeartWare." As alleged above, analysts agreed, reporting that "[t]he long-term potential and pipeline at HeartWare is reliant on the company's development of MVAD" (William Blair), that "HTWR's medium and long-term growth prospects are largely tied to MVAD" (Canaccord), and that "MVAD is key to [HeartWare's] long-term story" (Leerink). Similarly, as alleged above, Defendants routinely acknowledged that remediating the Warning Letter was one of the most important issues facing HeartWare during the Class Period, and that the CE Mark trial was a pivotal event for the Company. Accordingly, Defendants' misstatements concerning these critically important subjects, at a time when they were the focus of immense investor attention and concern, supports an inference of severe recklessness at a minimum, particularly given the egregiousness of the deficiencies, as described above.

187. Sixth, Defendants falsely claimed that the adverse events observed in the CE Mark trial were "typical of those seen in other clinical trials for ventricular assist devices," when they were in possession of data showing those adverse events were severe and highly unusual. Specifically, Defendants observed three pump thromboses in 11 CE Mark trial patients very shortly after they received MVAD implants (no later than three months after implantation). As discussed above, the incidence of pump thromboses observed in the CE Mark trial was between 7

and 13 times the event rate observed in "pivotal trials and postmarketing approval studies" of HeartMate II and in HVAD clinical trial data, and well in excess of the 0% thrombus rate associated with HeartMate III in clinical trial data published in September 2015. Likewise, these thromboses occurred unusually rapidly after implantation. Indeed, as discussed above, doctors and clinicians concluded, in the case of later HeartMate II implants, that an ***8%*** incidence of pump thrombosis in the first three months after implantation was unusual and dangerous, and were disturbed enough by their findings to communicate them publicly in the *NEJM*. Defendants here were witness to a far more disturbing trend. Yet, rather than publicly disclose the details of these adverse events (as did the *NEJM* authors) and suffer the same market share loss Thoratec endured after publication of the *NEJM* article, they misleadingly claimed that the events were "typical of those seen in other clinical trials for ventricular assist devices." In truth, the data in Defendants' possession contradicted that claim. Accordingly, their statements claiming the adverse events observed in the CE Mark trial were "typical," and their later statements continuing to tout MVAD's safety profile and commercial viability, from October 12, 2015 to the end of the Class Period, were made with scienter.

188. Seventh, Godshall knew or should have known about MVAD's severe deficiencies that persisted throughout the Class Period because these deficiencies were repeatedly discussed at meetings he attended, reflected in minutes of meetings he received, and were widely reported and discussed within HeartWare. As alleged above, deficiencies in the MVAD controller's software and alarms, controller display malfunctions, and the controller's propensity to dangerously overheat, among other problems with MVAD, were discussed at meetings Godshall attended. Moreover, defects in MVAD, including defects in the MVAD controller, were widely discussed within HeartWare, including at monthly meetings of MVAD's Project Oversight Board, which

Godshall "usually attended." Godshall also received minutes of all team meetings concerning MVAD, including weekly team meetings and specially convened engineering team meetings that were held as MVAD development ramped up, at which MVAD's deficiencies were routinely discussed in detail.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

189. During the Class Period, Defendants made a host of materially false and misleading statements and omissions during HeartWare's conference calls with investors and in the Company's SEC filings and press releases. Defendants' false statements generally fall into six principal categories: (1) statements representing that HeartWare was successfully remediating the deficiencies identified in the Warning Letter; (2) statements touting MVAD's flawed controller; (3) statements touting the dangerously defective qPulse algorithm; (4) unsupported claims about MVAD's safety profile, including the risk of pump thrombosis; (5) MVAD's progress in the CE Mark trial; and (6) assertions that the adverse events observed in the CE Mark trial were "typical" of those observed in other VAD trials.

A. Defendants' False and Misleading Statements During the Second Quarter of 2014

190. The Class Period begins on June 10, 2014, eight days after the FDA issued the Warning Letter to HeartWare. Beginning on that day, Defendants made a series of statements assuring investors that the Company was meaningfully remediating its manufacturing and quality assurance processes in response to the Warning Letter. Specifically, on June 10, 2014, Godshall attended the William Blair & Company Growth Stock Conference on HeartWare's behalf. At that conference, Godshall reassured investors that the Company had implemented, and was continuing to implement, far more rigorous manufacturing processes with respect to MVAD than those identified in the Warning Letter, stating,

> We are doing an assessment just to make sure if the FDA didn't like some stuff we did with HVAD, let's make sure that we're not doing the same stuff they didn't like with MVAD. So, we're doing a bit of a step back and taking a breath, looking at all the work we did with MVAD to make sure we can do our first in man in Canada as planned and then submit for CE Mark. And we're not anticipating a meaningful impact to that timeline, but we do want to make sure that sort of once you're in a hole, don't keep digging. ***And so far, the thoroughness with which we have approached MVAD is night and day relative to how we approached HVAD way back when we designed that product***.

191. Accordingly, Godshall told investors that "despite the warning letter, we actually see very little change to our plans" for MVAD's commercialization, and "we're not seeing any impact on our US launch" of MVAD.

192. On June 12, 2014, Godshall attended the annual Goldman Sachs Healthcare Conference on HeartWare's behalf. At that conference, an analyst specifically asked, "where are we with the MVAD development?" Godshall responded:

> So, in parallel with ***marshalling our resources to respond to the letter***, we also brought in a third-party objective reviewer and said, okay, look at the submission that we have and all the data we have on MVAD, and just make sure we didn't skip any steps. ***Make sure that if an FDA reviewer shows up in three months they don't say you are just stupid -- you had a warning letter and you did the same thing again***. And so we don't know that they are going to find anything, but if they find something we would want to mitigate it ***before we start any clinical activities so that we are more than squeaky clean***.

193. These statements persuaded analysts that HeartWare was taking serious steps to remediate the manufacturing and quality control deficiencies the FDA identified and to ensure that those deficiencies would not impact commercialization of MVAD. For instance, in a June 10, 2014 report, William Blair analysts stated, "We continue to have a favorable bias on [HeartWare] given the company's long-term outlook . . . . The company addressed the warning letter that was disclosed last week . . . . we get the sense that the company is being conservative (rightfully so) given that it has not encountered a warning letter in the past, and we do not anticipate a material impact to its results." Likewise, in a June 18, 2014 report, Wells Fargo analysts reported that

"MVAD Under Internal Review, But Expected To Remain On Track," and that "[m]anagement indicated that it's conducting internal evaluations to confirm that the issues prompted by the FDA warning letter will not similarly impact MVAD." Finally, in a June 30, 2014 report, Barclays analysts stated that "HTWR emphasized that all the issues involved quality management and suggested the risk of the [Warning Letter] impacting the MVAD trial timing was very low, in our view; all the issues are procedural and HTWR expects no commercial impact." These Barclays analysts also repeated Defendants' claim that "HTWR is continuously auditing itself to make sure it is following all SOP's and doesn't anticipate any material adverse impact."

194. Defendants' statements described in ¶¶190-92 were materially false and misleading when made. Contrary to Godshall's statements that HeartWare was "marshalling our resources to respond to the letter" and was working to resolve any problems "before we start any clinical activities [for MVAD] so that we are more than squeaky clean," in reality, the Company was taking no meaningful steps to remediate, and was not successfully remediating, the deficiencies identified by the FDA. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

195. For the same reasons, Defendants' statement that "the thoroughness with which we have approached MVAD is night and day relative to how we approached HVAD" was also materially false and misleading when made.

B. Defendants' False and Misleading Statements During the Third Quarter of 2014

196. On July 31, 2014, HeartWare held its second quarter earnings conference call with investors. On that call, Godshall continued to mislead investors about the Company's response to the Warning Letter and the Letter's impact on MVAD. Godshall stated:

> On the subject of the warning letter, ***from the moment it arrived, it became our highest priority***. We immediately began to shift energy, attention, and resources to address the observations. In the weeks since, ***we have made meaningful progress in reorganizing our leadership team, and commencing the upgrades of our processes***. We have completed program assessments to understand how this new more rigorous approach will affect our core pipeline projects, and we have infused our team with seasoned external experts to help supplement our skills and ***expedite the mitigation process***.

197. In response to an analyst's question asking, "what aspects of the warning letter impact MVAD specifically?" Godshall told investors that the FDA identified deficiencies in two processes that were integral to manufacturing the MVAD: (1) software validation; and (2) documentation and testing. Godshall stated that HeartWare was successfully remediating both areas:

> So as you walk through the four main categories of the warning letter validation, CAPAs, et cetera, one of the areas is the software validation work that you have to do on equipment that you use -- not on the system itself, but on the equipment they used to build the system, the product. And that is a fairly pervasive request by the agency, and we want to make sure that everything that we used to test and validate MVAD is up to standard.
>
> And ***we also have done a full review of all the other documentation and testing that we've done***. And we just want to ***make sure that there is no question about the integrity of the test reports that we have in-house, and so we're actively buttoning all that up as well***. So, incremental to the warning letter, we want to

> ***make sure that we are bulletproof when we submit and they don't suggest that there was a looseness, whether it's in test reports or validation work***.

198. On that call, Godshall highlighted the Company's remediation of its documentation and testing processes, telling investors that "we also have done a full review of all the other documentation and testing that we've done," and that the Company was working "to make sure that there is ***no question*** about the integrity of the test reports that we have in-house, and so we're ***actively buttoning all that up as well***."

199. An analyst, noting that "[t]he recent delays seem to be more about validation testing," asked HeartWare management to "give us more granularity to the last time changes were made -- any changes were made to the actual pump or the system, the electronics, the things the patient would interface with day to day?" Godshall responded by highlighting the Company's remediation efforts with respect to testing and validation "on the electronic side" in particular. Godshall stated,

> The other [aspect of changes made to MVAD], Mark Strong's impact[,] taking a guy who's spent 23, 24 years doing electronics, he saw a lot of stuff on the electronic side that we had an opportunity to improve on. Closing out test reports and the like, and so there was a lot of issues that had been justified or rationalized [rather than retested] that he has systematically for the last nine months been closing out.
>
> And ***so we are really tight now in terms of open issues that could have resulted in challenges from regulators***. Because they might have said, well why didn't you just repeat the test, or what have you, rather than justify the test. So [Senior Vice President] Mark [Strong] has really been ***buttoning up our approach on the electronic side*** quite commendably.

200. Another analyst asked Godshall to "confirm again on MVAD" that the Company was performing "the same sort of validation – testing and validation upgrades that you think are required for HVAD," and "talk a little bit more about specifically what you guys are going to be

doing over the next handful of months here on MVAD specifically." Godshall again assured investors that Heartware was successfully remediating any issues that impacted MVAD:

> Yes. So as I mentioned earlier, we -- the overall theme of the FDA audit and then subsequent communication with us is both ***make sure you're buttoned up on your documentation, make sure you're buttoned up on your validations***. And then in a specific area of validation, make sure you have specifically validated any of the equipment that's used to produce your product or measure your product and the like. And so there's -- that can cover a wide array of things that can be measuring equipment.
>
> * * *
>
> Additionally, as soon as we got the letter, we pulled aside a group including some external experts and said okay, do an audit of all of our documentation and all of our test reports, all of our findings. ***Make sure that we are really clean in terms of how we've written the test reports, what we've documented, how we've run the tests. Make sure we're compliant with all of the external standards, so that there's no -- we are not giving up any steps***.
>
> And so we've been working through that -- ***we worked through that internal audit process***, and did identify some things that we needed to clean up a little bit. ***And that's the parallel process that's going on right now to ensure that, again, there's no missing pieces***. Which, we were in very good shape, but not all the way there. And again, I think the integrity of the MVAD data is night and day relative to the data we had when we first submitted on HVAD.

201. On that July 31, 2014 earnings call, an analyst asked about MVAD's progress towards commercialization and HeartWare's ability to meet stated timelines given the Company's remediation efforts. In response, while he acknowledged the possibility that timelines would be delayed, Godshall further touted the success HeartWare was having in remediating MVAD's documentation and validation processes, claiming the Company was just "doing this last cleanup a bit on MVAD."

> That said, even though ***we're doing this last cleanup a bit on MVAD***, as our internal group looks at integrity of the MVAD documentation relative to the HVAD documentation that invited the FDA response, it's materially stronger than the work that we did on HVAD years ago that we're cleaning up now.
>
> If you drew a line from HVAD to where we'll be a year from now, post a warning letter response, ***MVAD is maybe three-quarters of the way there in terms of integrity***. And a lot closer to where we're ultimately going to be, therefore, the

> amount of activity we need to do to tighten up the MVAD program is much less which is why we think it's only a few months to get there.

202. Likewise, an analyst asked Godshall to compare the commercialization timelines for MVAD and another developmental product. Godshall told investors that while the other product needed further work, MVAD was "***so close to being done***."

> I don't think I'm going to have to make that choice [between prioritizing one developmental device over the other]. No one is going to put a gun to my head, I think we're going to get to do both thankfully. And I think MVAD is more complete, and ***so close to being done it's just buttoning it up and finishing*** the -- SYNERGY on the other hand, we are making modifications to the impeller geometry.

203. Defendants' statements convinced investors that although HeartWare was delaying the start of its CE Mark trial, it was making significant progress in addressing the issues raised by the Warning Letter. For example, in a July 31, 2014 report, Barclays analysts reported that HeartWare was taking a "prudent approach around documentation and validation[,] given its outstanding warning letter," and repeated the Company's statements that "MVAD documentation is 'materially stronger' than the work it did on HVAD a few years ago and MVAD is '75% there' in terms of integrity, making HTWR think a few months is a reasonable time frame." These Barclays analysts reported that HeartWare was taking steps to "ensure that everything used to test and validate MVAD is up to standard and there is no question about the integrity of the test reports that are in-house," and that "HTWR wants to be 'bulletproof' as it moves forward with the program." Cannacord analysts were similarly optimistic, stating that they were not "worried" by the delay in the CE Mark trial submission, and, given Defendants' encouraging statements, they "do not see any medium- to long-term impact to HTWR's revenue opportunities from this delay."

204. Defendants' statements described in ¶¶196-202 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had "made

meaningful progress" in addressing the Warning Letter, was "really tight now in terms of open issues that could have resulted in challenges from regulators," and that MVAD was "so close to being done," because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

205. For the same reasons, Defendants' statements that HeartWare was "actively buttoning [] up" its deficient manufacturing and quality control processes, that MVAD's testing and documentation was "materially stronger" than HVAD's, and that the Company was taking steps to "[m]ake sure that we are really clean in terms of how we've written the test reports, what we've documented, how we've run the tests [and that] we're compliant with all of the external standards" and "make sure that we are bulletproof when we submit [MVAD to regulators to initiate clinical trials]" were also materially false and misleading when made.

C. Defendants' False and Misleading Statements During the Fourth Quarter of 2014

206. On October 30, 2014, HeartWare held its third quarter earnings conference call. On that call, Godshall again underscored the success of HeartWare's remediation program, stating:

> Most importantly we have made significant progress in our effort to address the FDA warning letter issues. The warning letter remediation project is an enormous undertaking by so many of our employees and impacts every aspect of the Company. ***We have upgraded many of our key procedures and are already seeing a positive impact from the new approach***.
>
> ***We are working diligently through issues we find***, as is evidenced by our battery replacement effort which began a few months ago. This is not easy work and upgrading procedures, cleaning up documentation, and when necessary, replacing old product, is not the way we prefer to spend our days. But we believe that ***the new Company we are becoming is substantially more capable than the old Company we are leaving behind***.

207. On that same call, an analyst asked, regarding "the MVAD and as a corollary to that, the warning letter[:] What else do you need to do before you think you'll be in a position to file for the CE Mark trial? What's your confidence level around the timing there?" In response, Godshall stated that with respect to the Company's remediation efforts related to MVAD, "We are still at the final stages of documentation wrap-up, going through the formalities of things like design reviews that you have to do, prior to submission. So I'd say we're at final stages."

208. Later in his answer, Godshall further touted "how buttoned up we are being on the MVAD, given this refresh we've gone through as a result of the warning letter":

> I think in this case, particularly with how buttoned up we are being on the MVAD, given this refresh we've gone through as a result of the warning letter. I feel really confident that we will have the ability to answer questions that [regulators] come up with. The package of data we have now relative to the package of data we had for HVAD is night and day.

209. On that call, Godshall also assured investors that HeartWare's newly remediated testing and validation processes were showing highly promising results for MVAD. Godshall claimed, "Every data point we receive from bench testing, animal studies and physician commentary is that the MVAD will be paradigm-changing. We remain on track to file with regulators later this year or early next, the same timeframe as we described last quarter."

210. Again, analysts reacted positively to Defendants' soothing statements about MVAD. For example, Barclays analysts noted in an October 30, 2014 report, "Given HTWR has gone through a refresh as it mitigates the warning letter, HTWR feels 'very confident' in its package of data and ability to answer regulators' questions. In the 3Q, HTWR made significant progress in addressing FDA warning letter issues, noting that the majority of its deliverables are on track to be completed by year end. The process includes upgrading procedures, cleaning up documentation, and replacing old product where necessary." Similarly, in another October 30, 2014 report, Canaccord Genuity analysts stated that they were comforted by HeartWare's assurances its remediation process was essentially complete:

> Recall last quarter, the company decided to delay its CE Mark submission by approximately six months in order to improve upon several process/procedural issues following the receipt of the FDA warning letter. This quarter, management noted ***that the desired adjustments have been made, and they are currently wrapping up documentation for regulatory filing***. If we continue to follow this timeline out, and based off of a similar enrollment speed as seen in Thoratec's HeartMate III study, we continue to believe MVAD approval can come as early as H1:2016

211. Defendants' statements described in ¶¶206-209 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had "made significant progress in our effort to address the FDA warning letter issues," had "upgraded many of our key procedures," and that the Company's remediation efforts were "at the final stages" because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software

glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

212. For the same reasons, Defendants' statement that HeartWare was "already seeing a positive impact from" its remediation efforts was materially false and misleading when made.

213. For the same reasons, it was misleading for Godshall to state that the Company's supposedly rigorous testing showed "MVAD will be paradigm-changing" because the Company's severely deficient testing and validation procedures provided no reasonable basis for that assertion.

214. On November 20, 2014, Godshall attended the Canaccord Genuity Medical Technologies & Diagnostics Forum on HeartWare's behalf. At that conference, a Cannacord analyst asked Godshall, "[Y]ou had a warning letter that you wanted to make sure was taken care of before you got first in man [implantation with the MVAD] . . . . Where are we today with respect to MVAD? How confident are you that when you do your first in man that it's going to be as ready as it will ever be?" Godshall responded,

> Yes, I'm -- we have certainly never been more confident, and we are so anxious because ***we are finally really there***. Where it's now ***just tidying up final documentation***, getting everything packaged, getting it in front of competent authorities, and then soon thereafter in front of the FDA. So it's rather stunning, frankly, how well the device works considering how small it is.

215. Defendants' statements described in ¶214 were materially false and misleading when made. It was misleading for Godshall to claim that the Company had essentially completed remediation of the deficiencies raised by the FDA and was "just tidying up final documentation" because the Company was taking no meaningful steps to remediate the deficiencies identified by

the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

216. It was also misleading for Godshall to tout the Company's "confiden[ce]" in MVAD and trumpet "how well the device works." As noted above, at the time these statements were made, Defendants lacked a reasonable basis for their claims because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not detect design problems or provide a reliable assessment of the device's safety profile.

217. On December 10, 2014, Godshall attended the Oppenheimer Healthcare Conference on HeartWare's behalf. At that investor conference, Godshall misleadingly touted the MVAD's inadequately tested controller:

> [W]e're looking forward to having a chance to introduce this as well as the other MVAD features into the clinic early next year. One of which is a new controller . . . . So you have a much more user-friendly intuitive system with a simple touch screen display where you can interrogate the system. Very intuitive alarm conditions so that it will be easy for the patients to know what to do if there is a problem.

218. At that same December 10, 2014 conference, Godshall was asked whether MVAD was prone to pump thrombosis because of the small size of the device's impeller. In response, Godshall stated that the Company's testing of the device showed it had a superior pump thrombosis profile. Specifically, Godshall stated, "We have a hard time thrombosing the pump even when we sort of shove clot into it in a test fixture. It just sort of chews it up. So even when that's ingested, it doesn't seem to shut it down unless it's a really big organized clot, which is knock on wood, we think we're going to have a super low thromboembolic system both because of the structure of the blades and just the cleanliness of the fluid path."

219. Again, Defendants' statements persuaded investors that the device's supposedly revolutionary features would represent a significant advancement in patient care. For example, Credit Suisse analysts issued a January 9, 2015 report that stated, "We came away from our recent conversations with HTWR management impressed with the company's confidence in MVAD's flow capabilities & improvements in the design aimed at reducing thrombus & bleeding risk."

220. Defendants' statements described in ¶¶217-18 were materially false and misleading when made. It was misleading for Godshall to represent that MVAD's controller had "[v]ery intuitive" and "easy" "alarm conditions" because, as noted above in ¶¶94-95, 119-20, the controller's alarm was defective and exacerbated the risk of pump thrombosis.

221. It was likewise misleading for Godshall to state that the Company's testing showed MVAD was immune to pump thrombosis. As noted above, at the time these statements were made, HeartWare's testing and validation processes were severely deficient, and therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile. Indeed, as noted above in ¶¶90-125, HeartWare engineers had reported numerous problems with MVAD, including problems with the device's pump pressure algorithm and suction

alarm, which increased patients' risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

D. Defendants' False and Misleading Statements During the First Quarter of 2015

222. On February 26, 2015, HeartWare issued a press release announcing its fourth quarter and full-year 2014 financial and operating results. In that press release, HeartWare stated that it had "made significant upgrades to our quality systems."

223. Also on February 26, 2015, HeartWare held its fourth quarter and full-year 2014 earnings call. On that call, Godshall again emphasized the purported success HeartWare had experienced in "overhauling a major portion of our quality management system":

> We're looking forward to this important meeting, and in the coming weeks, we'll be sharing logistics of any events we might be hosting to discuss the myriad HVAD presentations there. I mentioned earlier that 2014 had both internal and external forces challenging us, and we used the year to grow stronger, including ***overhauling a major portion of our quality management system***. The systems we had in place at the start of 2014 were good enough for the smaller Company we had been, but were not sufficient for the more complex and larger Company we had become.
>
> ***The progress we have made thus far in remedying historical weaknesses is impressive***. The enhanced thoroughness has led to actions in the field, as we had predicted, and ***we are now better at identifying signals within our data that show us when we have opportunities to enhance our device's performance and safety***.
>
> Companies that go through this kind of systemic upgrade invariably experience this, and it seems likely that we will identify other opportunities that will also lead to actions in the field from time to time. It may seem counterintuitive, ***but these clean-up type activities of legacy issues are a clear sign of the improving strength and health of our quality system***, not a sign of its weakness. This should translate into better customer satisfaction ultimately, and far better predictability and pipeline execution as well. We expect that 2014 will be remembered as the year when ***we strengthened the foundation of the Company and put ourselves in a better position to succeed, well into the future***.

224. On that same earnings call, Godshall again touted the MVAD's controller, stating "Some docs are more enthusiastic about the PAL controller and the enhanced user friendliness for

the patient, and improved experience with a more sophisticated set of electronics than what's presently available."

225. Analysts continued to react positively to Defendants' statements. In a February 26, 2015 report, Barclays analysts, while stressing the importance of MVAD to HeartWare "as a long term value driver," stated that "MVAD updates were on track/positive." Canaccord analysts issued a report that same day, in which they similarly stated, "we expect next-generation devices from both HTWR (MVAD) and THOR (HM3) will be implanted in patients at an accelerating rate in clinical trials over the next 2 years, and we are bullish about the prospects for better patient outcomes from both devices ultimately . . . . [O]ur due diligence continues to lead us to the conclusion that given its size, ***if MVAD achieves the promise of lowering stroke and bleeding risk at the same time, it could ultimately become the market leading VAD***." The Canaccord analysts further stated,

> **MVAD on track.** We believe HTWR's medium and long-term growth prospects depend significantly on MVAD, and thus far, ***things seem to be progressing according to plan***. HTWR's update on MVAD during the conference call was positive and we note that this marks the second consecutive quarter without any delays in the clinical program, ***increasing our confidence*** the company will be able to adhere to the timelines for CE Mark approval and commencement of the U.S. IDE trial, which we anticipate for Q2 and Q4, respectively.

226. Likewise, Credit Suisse analysts issued a February 26, 2015 report stating that notwithstanding the release of negative HVAD data suggesting the device was associated with an increased risk of stroke, "HTWR struck a much more confident tone about the MVAD noting that the reduction in impeller mass & changes to the impeller shape will yield very low shear stresses despite high RPM's," and that as a result of Defendants' reassurances the analysts "remain optimistic that the MVAD will ultimately prove to be a very solid pump."

227. Defendants' statements described in ¶¶222-24 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had made "significant upgrades to our quality systems" and had "overhaul[ed] a major portion of our quality management system" because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

228. It was also misleading for Godshall to state that MVAD's controller would provide patients with an "improved experience" and had "a more sophisticated set of electronics than what's presently available" because, as alleged above at ¶¶90-125, the controller was defective and exacerbated the risk of pump thrombosis. Moreover, as noted above, at the time these statements were made, Defendants lacked any reasonable basis for their statements concerning the efficacy of the controller because HeartWare's testing and validation processes were severely deficient, and therefore could not support statements that the controller would provide patients with an "improved experience." Indeed, HeartWare engineers had reported numerous problems

with MVAD, including its controller and alarms, but these problems were ignored and quality assurance safeguards were circumvented.

229. On March 3, 2015, Godshall attended the annual Raymond James Institutional Investor Conference on HeartWare's behalf. At that conference, Godshall once again emphasized the MVAD's promising design features:

> The MVAD will be powered by our new controller called Pal. ***Pal has a tremendous number of advantages over other systems, including our own***. It's a single piece where you clip the battery under the bottom, so the patient now only has one cable, instead of multiple cables. It has a large battery on the inside of the controller, so that the controller itself can run the pump, while you are changing batteries. A touch screen display.
>
> It also has a driveline -- the primary part of the driveline for MVAD, that's outside the patient, will be actually be part of the controller. So if you have a problem with your driveline, you just change your controller. As opposed to having a problem with the driveline that is integrated into the pump. So, there are probably 30 other advantages to this that I won't go into, but ***every patient who we have shown it, can't wait to get it***.

230. At that same March 3, 2015 investor conference, Godshall also underscored MVAD's supposed immunity to pump thrombosis. Godshall stated, "we frankly can't thrombus, no matter how hard we try in the MVAD."

231. Defendants' statements described in ¶¶229-30 were materially false and misleading when made. It was misleading for Godshall to state that the Company could not "thrombus" the MVAD when testing it. As noted above, at the time these statements were made, Defendants lacked a reasonable basis for their assertions because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile. Indeed, as set forth above at ¶¶90-125, HeartWare engineers had reported numerous problems with MVAD, including problems with the device's pump pressure algorithm and suction alarm, which increased patients'

risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

232. It was also misleading for Godshall to state that MVAD's controller "has a tremendous number of advantages over other systems" because, as alleged above, the controller was defective and exacerbated the risk of pump thrombosis. In fact, as set forth above at ¶¶94-95, 119-20, the controller's alarm was defective and, therefore, posed a risk to patient safety. Moreover, as noted above, at the time these statements were made, Defendants lacked a reasonable basis for their claims because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes were not equipped to detect and remedy problems with MVAD's controller. Indeed, HeartWare engineers had reported numerous problems with MVAD, including its controller and alarms, but these problems were ignored and quality assurance safeguards were circumvented.

233. On March 10, 2015, Godshall attended the annual Barclays Healthcare Conference on HeartWare's behalf. At that conference, Godshall again stated that MVAD's technological superiority made patients less prone to adverse cardiovascular events – bleeds and thrombosis – than competing LVAD technology. Godshall stated:

> I think the biggest advantage that the MVAD is going to have over at least the HVAD is just the integrity of the fluid path. You've got much lower shear with MVAD than we have with HVAD even though it's spinning faster and people struggle to believe that a faster spinning and power could have lower shear, but it does. And ***that should translate into lower thromboembolic risk, and it will allow us to go with lower anticoagulation. If you can go with lower anticoagulation, you also decrease your bleeding risk***. So we think there is some real important synergy there.
>
> * * *
>
> So the big three of thrombus bleeding and infection, it feels really logical based on the design that you ought to see at least thromboembolic and infection improvement measurable. And then bleeding, you hope you're going to get that benefit. ***So we***

> ***believe that when you look at an adverse event table for MVAD compared to other devices, then it's going to be just demonstrably better*** and that in addition to the fact that it's kind of cool, sexy and small is why we're so excited about it.

234. Defendants' statements described in ¶233 were materially false and misleading when made. It was misleading for Godshall to state that MVAD would have a "demonstrably better" safety profile and "lower thromboemobolic risk" than other VADs because at the time these statements were made, Godshall lacked a reasonable basis for them. As noted above at ¶¶90-125, HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD that increased patients' risk of pump thrombosis and other adverse events, including problems with the device's software, electronics, alarms, and controller, but these problems were ignored and quality assurance safeguards were circumvented.

E. Defendants' False and Misleading Statements During the Second Quarter of 2015

235. On April 30, 2015, HeartWare held a conference call with investors to discuss the Company's first quarter 2015 financial and operating results. On that call, Godshall once again stated the Company was taking significant steps to improve its manufacturing and quality control processes. Godshall stated, "We continue to make very encouraging strides in the overhaul of our quality system, and our new leadership team has made a profound positive impact, and the feedback we've been getting from the agency over the past few months has been encouraging." Godshall further told investors, "it is hard to believe how close we are now" to getting MVAD commercialized.

236. Analysts were reassured by Defendants' statements and continued to report that MVAD's commercialization timeline was on track. In a May 1, 2015 report, for instance,

Canaccord analysts reported an "[e]ncouraging MVAD update," noting that although negative HVAD safety data had recently been published, "the positive MVAD update, namely a definitive target for FIM [first-in-man] in the European CE Mark trial, represents an initial step towards sentiment change." Likewise, Barclays analysts reported on April 30, 2015 that "MVAD remains on track . . . . Given our bullish view of MVAD, we remain OW."

237. Defendants' statements described in ¶235 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had made "very encouraging strides in the overhaul of our quality system" because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

238. On June 11, 2015, Godshall attended the annual Goldman Sachs Healthcare Conference on HeartWare's behalf. At that conference, Godshall was asked about whether he thought HeartWare would observe adverse events early on in the CE Mark trial. Godshall responded that given HeartWare's purported rigorous testing of MVAD, it was highly unlikely that problems with MVAD would materialize. Specifically, Godshall stated, "Well, so we've done

200 animals, plus, with MVAD. We can't even imagine what would go wrong, particularly -- the most likely issue would be with software. But we have just beat the heck out of this system over time, and we've made so many enhancements to the software we also can't imagine that we're going to find something in the clinic we haven't seen. But it's just be smart about it, make sure[.]"

239. At that same June 11, 2015 conference, an analyst asked how MVAD would solve the problems exhibited by prior and existing VAD technology that had stalled market growth. In response, Godshall stated that HeartWare's testing and validation processes showed the MVAD was less prone to pump thrombosis and other adverse events. Specifically, Godshall stated,

> And so, one, you should see less damage for red blood cells, which is stimulative to the clotting cascade. You should see less stimulation of platelets, also stimulative of clotting cascade. There's only two flow paths, so ***there's nowhere for a thrombus to form in [MVAD]***. ***And with the lighter load on the thrust bearing, that also should reduce any thromboembolic risk there. So pump thrombus should be lower. We have trouble thrombosing the thing; we can't seem to thrombose it. Even when we put it in a CircuLite system, where we know we can thrombose things, we still can't thrombose it***. And also -- so pump thrombus and downstream thrombus should both be measurably lower. Downstream thrombus is, obviously, a neurologic event and phenomenon.

240. Defendants' statements described in ¶¶238-39 were materially false and misleading when made. It was misleading for Godshall to tout the Company's rigorous testing and validation of MVAD, including the statement that HeartWare "just beat the heck out of this system," because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter

were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

241. It was also misleading for Godshall to state that HeartWare's testing showed MVAD was safe, including the statement that "we can't seem to thrombose" the MVAD. As noted above at ¶¶90-125, 145-46, 159-61, at the time this statement was made, MVAD posed an abnormally high risk of pump thrombosis. Moreover, Defendants lacked a reasonable basis for these statements because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD, including problems with the device's pump pressure algorithm and suction alarm, which increased patients' risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

F. Defendants' False and Misleading Statements During the Third Quarter of 2015

242. On July 20, 2015, HeartWare issued a press release announcing the Company's first human implantation of the MVAD. In that press release, HeartWare touted both the MVAD's controller and its qPulse algorithm. The press release stated, "the MVAD System incorporates a pulsatility algorithm called the qPulse™ Cycle that allows physicians to customize the device for each patient, providing four pulse settings designed to ***enhance aortic valve function and reduce chronic bleeding events***."

243. Analysts were encouraged by Defendants' enthusiastic statements about qPulse. BTIG analysts issued a July 20, 2015 report stating, "much of our Buy thesis has been based on

MVAD trials beginning and our view that investors will look favorably on this . . . and that HTWR's warning letter could be lifted." These analysts specifically highlighted Defendants' statements that MVAD's "Potential benefits include pulsatility . . . . [T]he pump will allow multiple pulsatile options, something we have long wondered about the availability of, and this could reduce GI bleeds and hemorrhagic strokes." Leerink analysts similarly noted that "[t]he MVAD . . . also incorporates a pulsatility algorithm called the qPulse Cycle – a beneficial feature that has the potential to reduce neurological events." Finally, JPMorgan analysts reported, "We continue to view MVAD as a potential game changer in the VAD market and see the risk/reward on HTWR shares as meaningfully skewed to the upside at current levels . . . . Based on our conversations with management, our sense is that enthusiasm for the pump is extremely high within Heartware."

244. Defendants' statements described in ¶242 were materially false and misleading when made. It was misleading for HeartWare to claim that the Company's qPulse algorithm would enhance MVAD's safety profile, because, as noted above, the algorithm was defective and exacerbated the risk of pump thrombosis. Moreover, as noted above, at the time these statements were made, Defendants lacked any reasonable basis for them because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not detect and remedy problems with MVAD's qPulse algorithm. Indeed, HeartWare engineers had reported numerous problems with MVAD's software and electronics, such as problems with the device's pump pressure algorithm, controller, and alarms, which increased patients' risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

245. On July 30, 2015, HeartWare held its second quarter earnings conference call. On that call, Godshall continued to emphasize HeartWare's progress in remediating its quality control, testing, and validation processes. Godshall stated, "During the quarter, we took additional measures that we expect will move us closer to remediation of the warning letter issued last year." Specifically with respect to MVAD, Godshall further stated, "We believe that MVAD represents compelling and innovative technology that will have a marked impact on reducing adverse event profiles and will improve patient quality of life."

246. Defendants' statements described in ¶245 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare "took additional measures" to successfully remediate deficiencies identified in the Warning Letter because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA, and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

247. It was also misleading for Godshall to state that he believed MVAD "will have a marked impact on reducing adverse event profiles and will improve patient quality of life." As noted above, at the time this statement was made, Godshall lacked a reasonable basis for it because

HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD that increased patients' risk of pump thrombosis and other adverse events, including problems with the device's software, electronics, alarms, and controller, but these problems were ignored and quality assurance safeguards were circumvented.

248. On August 13, 2015, Godshall attended the annual Cannacord Genuity Growth Conference on HeartWare's behalf. At that conference, an analyst asked Godshall to "summarize the last two years at MVAD, and why you took the steps you did." In response, Godshall emphasized, among other things, HeartWare's "major quality overhaul":

> The other big thing that happened -- so there's sort of three things. The third one is that we also realized, hey, our R&D leadership thing isn't really quite working well and particularly in the electronics area, and we brought in this guy, Mark Strong, who has ***totally overhauled our R&D procedures*** and shifted us out of the innovative, creative, entrepreneurial culture of R&D, but not really finishing stuff to ***heavy-duty execution and rigorous product development process***. And he also runs quality now. So we are also doing a ***major quality overhaul***.

249. Defendants' statements described in ¶248 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had undertaken a "major quality overhaul" and now had a "heavy-duty execution and rigorous product development process" because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual

software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change. Consequently, HeartWare's testing and validation processes were never sufficiently remediated, and could not detect design problems or provide a reliable assessment of MVAD's safety profile.

250. On September 1, 2015, HeartWare held a call with investors to announce the Valtech Transaction. On that call, Godshall made several statements designed to assuage investor concern over whether the Valtech Transaction signaled problems with HeartWare's critical MVAD launch. For instance, Godshall stated, "This transaction and the timing is only possible because of the strength of our core VAD business, as evidenced by several recent milestones. The MVAD System CE Mark clinical trial is now enrolling and, while we won't go into detail, we are quite delighted."

251. Likewise, an analyst asked Godshall to explain why the Company had decided to diversify away from VADs. In response, Godshall listed the purported benefits of the Valtech Transaction and denied that the transaction was motivated by the Company's lack of confidence in MVAD, stating, "we are only doing this because of our confidence in our VAD portfolio and pipeline, not because we are concerned about prospects of growth for VADs or concerned about prospects for our portfolio specifically."

252. Analysts were soothed by Defendants' statements. On September 2, 2015, Leerink analysts reported, "While this deal is likely to come as a surprise to most investors from a timing perspective, HTWR emphasized that it is in no way indicative of a lack of confidence in the

progression of the company's current LVAD business." Likewise, Barclays analysts stated that while "the size of this deal and timing will leave some investors scratching their heads," "HTWR was insistent that its LVAD portfolio (including MVAD) is doing very well (which we believe) . . . . Given our bullish view of MVAD, bolstered by recent FIM [first in man] implants and good anecdotal feedback thus far, we remain OW [overweight]."

253. Defendants' statements described in ¶¶250-51 were materially false and misleading when made. It was misleading for Godshall to emphasize the strength of MVAD and management's confidence in its commercial success when Defendants were not confident in MVAD's success, as evidenced by their attempt to consummate the Valtech Transaction as insurance against MVAD's failure. In fact, just days after making those statements, HeartWare was forced to halt the CE Mark trial due to MVAD's defective controller, and just weeks later, was forced to admit MVAD had caused a cluster of adverse events in the first 11 patients implanted with the device. At a minimum, Godshall lacked a reasonable basis to underscore management's purported confidence in MVAD because HeartWare's testing and validation processes were never sufficiently remediated, and therefore, the Company's quality assurance processes could not detect design problems or provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD, including its controller and electronics, but these problems were ignored and quality assurance safeguards were circumvented.

254. On September 9, 2015, Godshall attended the annual Wells Fargo Healthcare Conference and announced that deficiencies in HeartWare's manufacturing processes had led to problems with MVAD's controller, requiring HeartWare to pause the CE Mark trial. However, Godshall continued to state that HeartWare was making great strides in its remediation efforts, persuading investors that additional problems and delays were unlikely. Specifically, Godshall

stated, "Similarly on the commercial side, those folks who have tracked the Company realize we've been working through a warning letter, making phenomenal progress on that and as we uncover opportunities to improve our quality, we implement them."

255. At that September 9, 2015 investor conference, analysts asked Godshall if he "could talk about the features about MVAD you're most excited about? What your goals are with MVAD and how you feel at this point, very early stage about meeting those goals?" In response, Godshall underscored MVAD's supposedly strong safety profile and the device's promising performance in the CE Mark trial, stating,

> Yes. So my goal was to finish the CE trial in January, now it feels like -- more like February or March once we come back online. And ***my expectation is that this is going to be a device that has dramatically lower adverse events than certainly what we've seen historically as a field, not just as a company***.
>
> I don't see anything [in the CE Mark trial] that tells me I'm wrong, but it's also early. And even if I felt comfortable giving a blow by blow clinical update on every patient, it could be a bit misleading to say, okay, we have a patient out seven weeks and he's doing great. Therefore you conclude that every patient is going to do great, but ***we haven't seen anything that says to us, "okay, we're going to have to compromise our expectations" and think that this is going to have an adverse event profile that is analogous to current generation devices***.

256. Also at the September 9, 2015 investor conference, Godshall continued to reassure investors that the Valtech Transaction did not signal anything negative about MVAD. Godshall stated, "And there was a misperception that concerns about MVAD drove Valtech -- couldn't be further from the truth. Confidence in MVAD gave us confidence to create a broader heart failure company around the MVAD platform and now expanding into the ability to treat mitral disease and ultimately have a replacement for mitral and treat tricuspid disease. And we knew that there was going to be some education process required to get everybody sat around to why does this make sense for HeartWare."

257. Finally, at the September 9, 2015 investor conference, Godshall again stated that progress in the CE Mark trial was promising and emphasized that MVAD's pump had been rigorously tested, stating,

> With all of the news surrounding HeartWare over the past week, ***I just want to make sure that everybody is clear that the enthusiasm we have for MVAD has never been higher***. We have 11 patients enrolled in our trial so far internationally. ***We are thrilled with how the device is performing***. Larry has probably asked me in the past what keeps me up at night, what do I worry about with MVAD and on the pump side, we tested it so much that we really weren't worried and I think it suggests ***we have good reason for not having being worried. We're really pleased with the result so far***.
>
> * * *
>
> So, ***universally positive reaction*** to the pump itself and the controller has people actually almost as excited or more excited than the pump. So, ***so far, it's been a very validating experience in the clinic***, but it's also early. So we've still got to prove our beliefs in a larger patient set and over longer period of time, but ***so far so good***.

258. Analysts were comforted by Defendants' statements. For instance, Piper Jaffray analysts issued a September 9, 2015 report stating,

> While the delay and its timing are both less than ideal, the news that the issue was associated with the controller vs. the MVAD pump itself (along with the update that the 11 patients implanted in the CE Mark trial to date are doing well) ***significantly reduces the risk associated with the pause in trial enrollment in our view***. Management again emphasized that the recent Valtech deal is not a hedge against MVAD and stated that physician excitement and demand around MVAD remain robust

Likewise, Canaccord analysts stated that while "management today announced a voluntary pause of trial enrollment in their ongoing MVAD CE Mark clinical trial," "We would highlight that these issues pertain solely to the controller and do not impact pump performance, a critical differentiation, in our view." William Blair analysts reported, "We spoke with the company which stated that the issues have not been seen in study devices and do not affect pump performance; therefore, we should not see any long-term impact to MVAD adoption."

259. Defendants' statements described in ¶¶254-57 were materially false and misleading when made. It was misleading for Godshall to state that the Company was "making phenomenal progress" remediating the deficiencies identified in the Warning Letter, and to state that MVAD had been rigorously "tested" and this testing showed HeartWare had "good reason for not having [been] worried" about MVAD's performance, because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

260. It was also materially false and misleading for Godshall to tout MVAD's supposedly strong safety profile, and to state, "my expectation is that this is going to be a device that has dramatically lower adverse events than certainly what we've seen historically as a field, not just as a company." As noted above at ¶¶90-125, 145-46, 159-61, at the time these statements were made, MVAD posed an abnormally high risk of pump thrombosis. At minimum, at the time these statements were made, Defendants lacked a reasonable basis for them because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not provide a reliable assessment of MVAD's safety profile.

Indeed, as set forth above at ¶¶90-125, HeartWare engineers had reported numerous problems with MVAD, including problems with the device's pump pressure algorithm and suction alarm, which increased patients' risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

261. Godshall's statements that HeartWare's "confidence in MVAD" drove the Valtech Transaction were also materially false and misleading when made because Defendants were not confident in MVAD's success, as evidenced by the Valtech Transaction itself. In fact, just weeks after making those statements, HeartWare was forced to admit MVAD had caused a cluster of adverse events in the first 11 patients implanted with the device. At a minimum, Godshall lacked a reasonable basis to underscore management's purported confidence in MVAD because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not detect and remedy design problems or provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD, including its controller and electronics, but these problems were ignored and quality assurance safeguards were circumvented.

262. It was also misleading for Godshall to state that HeartWare was "thrilled" with the progress of the CE Mark trial, that the trial had been a "very validating experience" for MVAD, that there had been a "universally positive reaction" to the device in the clinic, and represent that the trial had not revealed serious problems with MVAD, because serious problems with the MVAD were already evident in the CE Mark trial. As noted above at ¶125, at the Company's first German implantations, surgeons "had to tape the connector and controller to each other" to prevent MVAD from falling apart and observed that MVAD "did not deliver enough flow."

G. Defendants' False and Misleading Statements During the Fourth Quarter of 2015

263. On October 12, 2015, analysts began to report on rumors that HeartWare had observed a cluster of adverse events in the first 11 patients in the CE Mark trial, triggering significant market concern and causing HeartWare's stock price to decline. In response to those reports, HeartWare was forced to acknowledge the existence of adverse events. Thus, on October 12, HeartWare posted a statement on the Investor Relations section of its corporate website (and filed that statement on a Form 8-K with the SEC the next day), in which the Company announced it would further delay the CE Mark trial in order to analyze "reported adverse events in certain clinical trial patients." The Company did not disclose the number or nature of adverse events at issue. Instead, the Company assured investors that the adverse events were not unusual. Specifically, the Company's Form 8-K stated, "[t]he events being analyzed are typical of those seen in other clinical trials for ventricular assist devices."

264. Defendants' statement described in ¶263 was materially false and misleading when made. It was misleading for Defendants to state that the adverse events observed in the CE Mark trial "are typical of those seen in other clinical trials for ventricular assist devices" because (1) the events that occurred were pump thromboses – serious adverse events that were of particular concern to investors; (2) the 27% incidence of pump thrombosis observed in the CE Mark trial was unusually high: 7 to 13 times the incidence reported in early clinical trials of competing devices that drove VAD market growth, and at least 3 times the incidence reported in the alarming *NEJM* study that caused the VAD market to stagnate; and (3) the pump thromboses occurred unusually quickly after device implantation, and 6 times faster than reported in competing devices and more than twice as fast as HeartWare's extant VAD, HVAD, as set forth above at ¶¶145-46, 159-61.

265. On October 29, 2015, HeartWare issued a press release announcing its third quarter financial and operating results. Although the press release acknowledged that MVAD patients in the CE Mark trial had experienced adverse events, HeartWare and Godshall downplayed the significance of those adverse events. Defendants stated, "We are also reviewing reported adverse events, which are ***typical of those seen in other clinical trials for ventricular assist devices***, and we are confident that we will resolve the issues in order to resume the MVAD CE Mark clinical trial. The MVAD System represents an important advancement in next generation technology, and clinicians around the world remain eager to gain access to this innovative, novel device."

266. On October 29, 2015, HeartWare also held a conference call with investors to discuss the Company's third quarter financial and operational results. On that call, Godshall continued to state that there was no need for concern about the CE Mark trial: "We are encouraged by our initial findings from the clinical and technical review and presently we do not see any evidence that a redesign will be warranted."

267. On that same October 29, 2015 earnings call, Godshall continued to downplay the controller problems that forced HeartWare to pause the CE Mark trial and the seriousness of the adverse events the Company had already observed in just the first few MVAD patients: "Fortunately, our initial experience [in the CE Mark trial] has us more convinced than ever that the MVAD will be extremely successful in the clinic and ultimately in the marketplace. As a reminder, the trial is actually paused because of the control[ler] issue not a pump issue."

268. Godshall also assured investors that the Company was successfully remediating the issues identified by the FDA, stating, "the MVAD status may give the impression that execution is challenged at HeartWare, but this couldn't be further from the truth. Between MVAD, warning

letter and HVAD enhancement, our internal execution has never been stronger and our team deserves a tremendous amount of credit for their exceptional work."

269. While analysts were concerned about reports of adverse events in MVAD patients in the CE Mark trial, they were comforted by Defendants' statements. For instance, William Blair analysts issued an October 29, 2015 report stating that, "Management gave a positive update on MVAD on the call, saying that it is working to resolve the manufacturing issues with the product's controller and hopes to resume production of MVAD next month. The company is close to finalizing changes to the controller, but may need to tighten manufacturing specifications on the pump itself, depending on the outcome of the continuing review, but it seems more likely than not to resume normal production soon." Leerink analysts similarly stated in an October 30, 2015 report,

> HTWR management did provide an MVAD update on the call, noting that their own internal investigation has led them to believe that tightening manufacturing specifications could be enough to improve pump performance and prompt a trial restart. CEO Doug Godshall noted that, as of right now, he does not believe any design change or tweak is warranted, which jives with our recent MEDACorp physician checks . . . . We reiterate our OP rating given our view that the shares now adequately reflect the clinical risk associated with HTWR's next-gen MVAD

270. Defendants' statements described in ¶¶265-68 were materially false and misleading when made. It was misleading for Godshall to state that the adverse events observed in the CE Mark trial "are typical of those seen in other clinical trials for" VADs because (1) the events that occurred were pump thromboses – serious adverse events that were of particular concern to investors; (2) the 27% incidence of pump thrombosis observed in the CE Mark trial was unusually high: 7 to 13 times the incidence reported in early clinical trials of competing devices that drove VAD market growth, and at least 3 times the incidence reported in the alarming *NEJM* study that caused the VAD market to stagnate; and (3) the pump thromboses occurred unusually quickly after

device implantation, and 6 times faster than reported in competing devices and more than twice as fast as HeartWare's extant VAD, HVAD, as set forth above, at ¶¶145-46, 159-61.

271. Godshall's statements that "[w]e are encouraged by our initial findings from the clinical and technical review and presently we do not see any evidence that a redesign will be warranted," and that "our initial experience [in the CE Mark trial] has us more convinced than ever that the MVAD will be extremely successful in the clinic and ultimately in the marketplace" were also materially false and misleading. Contrary to Godshall's statements, the CE Mark trial provided data showing that MVAD posed a severe risk of pump thrombosis, which demonstrated the device was fundamentally flawed and its commercial prospects were in grave jeopardy. Specifically, (1) HeartWare observed 3 cases of pump thrombosis, which were serious adverse events that were of particular concern to investors; (2) the 27% incidence of pump thrombosis observed in the CE Mark trial was unusually high: 7 to 13 times the incidence reported in early clinical trials of competing devices that drove VAD market growth, and at least 3 times the incidence reported in the alarming *NEJM* study that caused the VAD market to stagnate; and (3) the pump thromboses occurred unusually quickly after device implantation, and 6 times faster than reported in competing devices and more than twice as fast as HeartWare's extant VAD, HVAD. At a minimum, in light of these facts, Defendants had no reasonable basis for their statements.

272. It was also misleading for Godshall to state that the Company's "internal execution has never been stronger," and to deny that "execution is challenged at HeartWare" because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not successfully remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its

software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

273. On November 5, 2015, HeartWare held its International Analyst and Investor Meeting. At that conference, Godshall continued to downplay the adverse events the Company had observed in the CE Mark trial: "We continue to investigate some of the adverse event issues that we identified in a small number of patients in our trial. At this point, we still see no anticipation for design modification based on the overall performance."

274. On November 11, 2015, Godshall attended the annual Credit Suisse Healthcare Conference on HeartWare's behalf. At that conference, Godshall continued to reassure investors that there was no evidence the MVAD pump would have to be redesigned. Godshall stated,

> And we started with about 150 variables, both clinical and technical, and have narrowed that down to a very small handful that we may choose to tighten up in terms of things like manufacturing tolerances. At this juncture, ***we don't see any evidence that any design change to the pump is warranted***.

275. Defendants' statements described in ¶¶273-74 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare did not see "any evidence that any design change to the pump is warranted," and that the Company was investigating "a small number of" adverse events and did not anticipate the need for "a design modification based on the overall performance." Contrary to Godshall's statements, the CE Mark trial provided data showing that MVAD posed a severe risk of pump thrombosis, which demonstrated the device was

fundamentally flawed and its commercial prospects were in grave jeopardy. Specifically, (1) HeartWare observed 3 cases of pump thrombosis, which were serious adverse events that were of particular concern to investors; (2) the 27% incidence of pump thrombosis observed in the CE Mark trial was unusually high: 7 to 13 times the incidence reported in early clinical trials of competing devices that drove VAD market growth, and at least 3 times the incidence reported in the alarming *NEJM* study that caused the VAD market to stagnate; and (3) the pump thromboses occurred unusually quickly after device implantation, and 6 times faster than reported in competing devices and more than twice as fast as HeartWare's extant VAD, HVAD. At a minimum, in light of these facts, Defendants had no reasonable basis for their statements.

276. At the November 11, 2015 Credit Suisse Healthcare Conference, Godshall also continued to promote MVAD's qPulse feature, and made unsupported statements about its supposed ability to enhance MVAD's safety profile. Godshall stated,

> MVAD will also have a pulsatility algorithm that we believe will enhance washing of the ventricle and enable the aortic valve to continue to fire throughout the cardiac cycle more regularly, which should have a benefit in terms of reduced aortic insufficiency. And physicians generally prefer some pulse versus no pulse. So, being able to dial it in through the system is very helpful.

277. On November 19, 2015, Godshall attended the annual Canaccord Genuity Medical Technology & Diagnostics Forum. At that conference, Godshall stated with respect to the qPulse algorithm, "And within the electronics, we have a pulsatility algorithm called qPulse . . . [which is] designed to both enhance washing of the ventricle as well as hopefully improve aortic valve function. Right now a lot of patients end up with aortic valve insufficiency because their valve doesn't fire through the cardiac cycle. QPulse should further improve aortic valve function."

278. Defendants' statements described in ¶¶276-77 were materially false and misleading when made. It was misleading for Godshall to tout the benefits of the qPulse algorithm, including

that "QPulse should further improve aortic valve function," because, as noted above, the algorithm was defective and exacerbated the risk of pump thrombosis. Moreover, as noted above, at the time these statements were made, Godshall lacked a reasonable basis for them because HeartWare's testing and validation processes were never sufficiently remediated, and, therefore, the Company's quality assurance processes could not detect and remedy problems with MVAD's qPulse algorithm. Indeed, HeartWare engineers had reported numerous problems with MVAD's software and electronics, such as problems with the device's pump pressure algorithm, controller, and alarms, which increased patients' risk of pump thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

279. At the November 19, 2015 Canaccord Genuity Medical Technology & Diagnostics Forum, Godshall specifically stated HeartWare had focused on, and fixed, any problems with the MVAD's software and electronics, which were all minor.

> ***We also over that time realized that we needed to upgrade our software which we're working on and we'll be submitting, should have all the data to submit on the software design upgrades. It's really just fixing some bugs we discovered and we should have all that data middle of December***.
>
> And on the pump side we have indicated that we're looking at some adverse events that we noticed in our clinical trial. Part of this is when you only have 11 patients, any adverse event you have is nearly a 10% event rate. So while we were paused it gave us an opportunity to evaluate whether there are our opportunities to further enhance pump performance.
>
> That investigation is ongoing, so parallel track. ***We fixed the electronics*** and now we're just trying to determine if there are any enhancements we want to make in terms of specifications to the pump. We are not seeing anything that suggests that we will need to change the fundamental pump design which would be a much longer term project.

280. Defendants' statements described in ¶279 were materially false and misleading when made. It was misleading for Godshall to state that HeartWare had remediated its manufacturing, testing, and validation deficiencies and "fixed the [MVAD's] electronics," because

the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and was not remediating those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

281. At the November 19, 2015 Canaccord investor conference, analysts specifically asked Godshall what he would say "to shareholders that are deciding whether or not to vote on the [Valtech Transaction] as to why it's good for HeartWare?" In response, Godshall stated the Valtech Transaction would diversify HeartWare and again reassured investors that the deal did not portend a negative outcome on MVAD: "We feel great about our company as a VAD company and did not do this [Valtech Transaction] because of fear of failure of MVAD or HVAD or Longhorn or CircuLite."

282. Defendants' statements described in ¶281 were materially false and misleading when made. It was misleading for Godshall to state that "[w]e feel great about our company as a VAD company and did not do this [Valtech Transaction] because of fear of failure of MVAD" because Defendants were not confident in MVAD's success, as evidenced by the Valtech Transaction itself. At a minimum, Godshall lacked a reasonable basis to underscore management's purported confidence in MVAD because HeartWare's testing and validation processes were never

sufficiently remediated, and therefore, the Company's quality assurance processes could not detect and remedy design problems or provide a reliable assessment of MVAD's safety profile. Indeed, HeartWare engineers had reported numerous problems with MVAD, including its controller and electronics, but these problems were ignored and quality assurance safeguards were circumvented.

283. On December 1, 2015, Godshall attended the annual Piper Jaffray Healthcare Conference. At that conference, Godshall continued to assure investors that HeartWare had vigorously tested MVAD and that there were no problems in the MVAD design. Godshall stated, "We remain very optimistic that the core design is actually quite excellent and that given the overall performance of the pump and a lot of incremental testing that we've done to give ourselves comfort around the pump performance and fluid dynamics of the system. So, we continue to believe that the MVAD will be a very strong pump clinically and commercially when it reemerges." Likewise, an analyst asked Godshall what gave him confidence that HeartWare could stay within "the [manufacturing] specs" for MVAD and would not have to go "back to the drawing board" with the device. While Godshall acknowledged that testing and validation deficiencies contributed to delays and problems MVAD had experienced to date, he responded by touting HeartWare's newly remediated manufacturing processes, stating that "what we have found as we look at our manufacturing records is ***we have tremendous control over our processes***," and that "[***w***]***e measure everything now***."

284. On December 8, 2015, Godshall attended the annual Oppenheimer Healthcare Conference. At that conference, Godshall continued to promote the MVAD on the basis of its qPulse algorithm, stating, "Within the controller, we have a software algorithm called qPulse, which has three settings for variable speed adjustments. This is designed to provide not a synchronized pulse for the patient, but a regular-enough pulse that enables the native ventricle to

eject blood, which then enables the aortic valve to open and close, which we believe should reduce the rates of aortic valve insufficiency."

285. Again, analysts were comforted by Defendants' soothing statements. For instance, JPMorgan analysts noted in a January 8, 2016 report, "MVAD's own progress was interrupted first by a controller assembly issue and then more ominously by a cluster of thrombotic events in the early European experience . . . . However, given our expectation that MVAD will return to the clinic in the first quarter, we view the risk/reward as favorable at current levels. As a result, we are maintaining our Overweight rating on the stock."

286. Defendants' statements described in ¶¶283-84 were materially false and misleading when made. It was misleading for Godshall to state that "[w]e remain very optimistic that the core design is actually quite excellent and that given the overall performance of the pump . . . we continue to believe that the MVAD will be a very strong pump clinically and commercially." Contrary to Godshall's statements, the CE Mark trial provided data showing that MVAD posed a severe risk of pump thrombosis, which demonstrated the device was fundamentally flawed and its commercial prospects were in grave jeopardy. Specifically, (1) HeartWare observed 3 cases of pump thrombosis, which were serious adverse events that were of particular concern to investors; (2) the 27% incidence of pump thrombosis observed in the CE Mark trial was unusually high: 7 to 13 times the incidence reported in early clinical trials of competing devices that drove VAD market growth, and at least 3 times the incidence reported in the alarming *NEJM* study that caused the VAD market to stagnate; and (3) the pump thromboses occurred unusually quickly after device implantation, and 6 times faster than reported in competing devices and more than twice as fast as HeartWare's extant VAD, HVAD. At a minimum, in light of these facts, Defendants had no reasonable basis for their statements.

287. It was also misleading for Godshall to represent that HeartWare had remediated its manufacturing, testing, and validation deficiencies (including that HeartWare had "tremendous control over our processes" and "measure[d] everything now"), and to cite the Company's "incremental testing" as providing "comfort" about MVAD, because the Company was taking no meaningful steps to remediate the deficiencies identified by the FDA and had not remediated those deficiencies. Indeed, HeartWare's manufacturing, testing, and validation processes remained riddled with severe deficiencies. As detailed above at ¶¶90-125, (1) HeartWare engineers had reported numerous problems with MVAD, including its software and electronics, but these problems were ignored and quality assurance safeguards were circumvented; (2) HeartWare's devices exhibited unusual software glitches, yet MVAD lacked any validation of its electrical controls; (3) the deficiencies identified in the FDA's Warning Letter were so severe they would take years to adequately remediate; and (4) the manufacturing and validation changes HeartWare implemented after receiving the Warning Letter were, at best cosmetic, and, for the most part, HeartWare's manufacturing, testing, and validation procedures did not change.

288. It was also misleading for Godshall to represent that the qPulse algorithm should improve MVAD's safety profile because, as noted above, the algorithm was defective and exacerbated the risk of pump thrombosis, as evidenced by the adverse event data Defendants observed in the CE Mark trial. At a minimum, at the time this statement was made, Defendants lacked any reasonable basis for it because HeartWare's testing and validation processes were never sufficiently remediated, and therefore, the Company's quality assurance processes could not detect and remedy problems with MVAD's qPulse algorithm. Indeed, HeartWare engineers had reported numerous problems with MVAD's software and electronics, such as problems with the device's pump pressure algorithm, controller, and alarms, which increased patients' risk of pump

thrombosis and other adverse events, but these problems were ignored and quality assurance safeguards were circumvented.

VIII. LOSS CAUSATION

289. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiff and the Class. Throughout the Class Period, HeartWare's stock price was artificially inflated as a result of Defendants' materially false and misleading statements and omissions that created the false impression, among other things, that (i) HeartWare was adequately and successfully remediating the manufacturing, testing, and validation deficiencies identified in the Warning Letter; (ii) the deficiencies identified in the Warning Letter would not impede MVAD's commercialization; (iii) MVAD, including its core controller and qPulse features, had been manufactured, tested, and validated in compliance with cGMP; (iv) statements about MVAD's safety profile, including its propensity to cause pump thrombosis, were accurate and supported by validation and testing that was in compliance with cGMP; (v) that the interim results of the CE Mark trial were promising, and any adverse events observed were consistent with those observed in other VAD trials and did not indicate a design flaw with the pump or jeopardize MVAD's commercial success; and (vi) HeartWare's newly-remediated validation and testing processes further indicated the device was commercially viable.

290. Multiple separate disclosures on these topics revealed to the market on a piecemeal basis the false and misleading character of Defendants' statements and omissions. First, on September 1, 2015, after the close of trading, Defendants disclosed their intention to consummate the Valtech Transaction – a highly dilutive transaction whereby HeartWare shareholders would give up approximately 35% of the Company's equity just months before the value of their shares was ostensibly set to increase when MVAD was brought to market. This announcement partially revealed the truth concealed by Defendants' misstatements, as the market understood that the

Valtech Transaction called into question Defendants' prior representations concerning HeartWare's remediation of deficiencies identified by regulators and MVAD's commercial viability. Accordingly, HeartWare's stock price declined in response to this announcement, and some of the artificial inflation caused by Defendants' materially false and misleading statements and omissions was removed, thereby causing damage to Lead Plaintiff and other members of the Class. Specifically, HeartWare stock fell by 21%, from $81.81 at the close of trading on September 1 to $64.82 at the close of trading on September 2, on heavy volume of more than 4.3 million shares (compared with an average volume of 270,000 shares traded per day over the previous three months).

291. However, HeartWare's September 1, 2015 disclosure did not reveal the full truth to investors. Defendants continued to mislead investors about MVAD, thus preventing the market from learning the full extent of Defendants' failure to remediate their internal manufacturing and quality assurance processes, the ramifications of that failure, and the truth about MVAD's safety profile and commercial viability. Specifically, Defendants denied the Valtech Transaction signaled problems with MVAD; rather, Defendants stated that "we are only doing this because of our confidence in our VAD portfolio and pipeline." Further, Defendants stated the Company was "delighted" by progress of the CE Mark trial.

292. Second, on October 12, 2015, Defendants were forced to disclose that they had observed adverse events in the CE Mark trial and would further delay resumption of the trial in order to investigate them. Defendants' failure to disclose HeartWare's deficient manufacturing and quality assurance processes concealed from investors the risk that MVAD's unsafe design would cause such adverse events, despite Defendants' repeated assurances that they could not "thrombus" the pump. With Defendants' disclosures that the Company had observed adverse

events in just 11 patients, some of this concealed risk materialized. Thus, the truth concealed by Defendants' materially false and misleading statements and omissions was partially revealed, as Defendants' disclosures further signaled to the market that MVAD had not been subjected to the rigorous testing and validation Defendants claimed, and raised questions about its safety profile and commercial viability. Some of the artificial inflation caused by Defendants' misstatements was removed, thereby causing damage to Lead Plaintiff and other members of the Class. Specifically, in response to the October 12, 2015 disclosures, HeartWare shares plunged nearly 30%, from $50.07 per share on October 9, 2015 to $35.21 per share on October 13, 2015, on heavy volume of approximately 1.6 million shares traded on October 12 and 6.1 million shares traded on October 13.

293. As before, however, HeartWare's disclosure failed to reveal the full truth to investors. Defendants reassured investors that (1) "[t]he events being analyzed are typical of those seen in other clinical trials for ventricular assist devices"; (2) HeartWare had made great progress in remediating its manufacturing, testing, and validation deficiencies, (3) its newly-remediated quality assurance processes showed that the device design was sound and that it was unlikely MVAD would continue to be plagued by problems going forward; and (4) the qPulse algorithm (which Defendants knew or should have known was inadequately tested) was strong and commercially promising.

294. Third, On January 11, 2016, the complete truth about MVAD's dangerous safety profile, the device's defects, and HeartWare's failure to remediate the manufacturing, testing, and validation deficiencies identified by the FDA's Warning Letter was finally disclosed. That day, the Company revealed that nearly half of the patients implanted with MVAD experienced pump thrombosis, that the dangerously defective qPulse algorithm and faulty suction alarm appeared to

increase the risk of pump thrombosis, and that the trial would be paused indefinitely (and might have to be restarted) to investigate this and other design and manufacturing defects. Among other things, MVAD's qPulse algorithm caused patients to experience unusually prolonged suction events, and the device's suction alarm failed to detect the suction event despite the fact that it would last for weeks and even months.

295. As discussed above, the adverse events Defendants reported on January 11, 2016 were the result of Defendants' failure to remediate the deficient manufacturing, testing, and validation practices identified in the Warning Letter, including testing and validation of MVAD's software and electronics. Defendants' failure to disclose HeartWare's deficient manufacturing and quality assurance processes, their unsupported statements concerning MVAD's purportedly strong safety profile, and their false assurances that the adverse events were "typical," concealed from investors the risk that MVAD's design was actually unsafe, and that the device was not commercially viable. With Defendants' January 11, 2016 disclosures, this risk had fully materialized, revealing to investors the truth and removing the remaining artificial inflation in HeartWare's stock caused by those misstatements. Specifically, in response to the January 11, 2016 disclosures, HeartWare shares plunged more than 35%, from $40.84 per share on January 11, 2016 to $26.50 per share on January 12, 2016, on heavy volume of more than 7 million shares traded.

296. In all, disclosures of the true facts concerning HeartWare's remediation of its manufacturing, testing, and validation processes, MVAD's performance in the CE Mark trials, and the safety and approval obstacles facing MVAD commercialization caused massive losses to investors, with HeartWare shares falling nearly 68%, from $81.81 per share at the close of trading on September 1, 2015, to $26.50 per share at the close of trading on January 12, 2016.

297. It was entirely foreseeable that Defendants' materially false and misleading statements and omissions discussed herein would artificially inflate the price of HeartWare's securities. It was also foreseeable to Defendants that the revelation of the truth about MVAD and HeartWare's manufacturing and quality control processes would cause the price of the Company's securities to fall as the artificial inflation caused by Defendants' misstatements and omissions was removed. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false and misleading statements and omissions.

IX. PRESUMPTION OF RELIANCE

298. At all relevant times, the market for HeartWare's securities was efficient for the following reasons, among others:

(a) HeartWare's stock met the requirements for listing, and was listed and actively traded on Nasdaq, a highly efficient and automated market;

(b) As a regulated issuer, HeartWare filed periodic reports with the SEC and Nasdaq;

(c) HeartWare regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) HeartWare was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public market place.

299. As a result of the foregoing, the market for HeartWare stock promptly digested current information regarding HeartWare from all publicly available sources and reflected such information in HeartWare's stock price. Under these circumstances, all purchasers of HeartWare securities during the Class Period suffered similar injury through their purchase of HeartWare securities at artificially inflated prices, and a presumption of reliance applies.

300. In addition, Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

301. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements described in this Complaint. Many of the specific statements described herein were not identified as "forward-looking" when made. To the extent that there were any forward-looking statements, there was no meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements described herein, Defendants are liable for those false forward-looking statements because at the time each was made, the particular speaker knew that the particular forward-looking statement was false or misleading, and/or that the forward-looking statement was authorized and/or approved by an executive officer of HeartWare who knew that those statements were false or misleading when made.

XI. CLASS ACTION ALLEGATIONS

302. Lead Plaintiff brings this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a class consisting of all those who purchased or otherwise acquired HeartWare securities between June 10, 2014 and January 10, 2016, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of HeartWare at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

303. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, HeartWare common shares were actively traded on Nasdaq. As of December 31, 2015, HeartWare had approximately 17,533,606 shares of common stock outstanding. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds or thousands of members of the proposed Class. Class members who purchased HeartWare common shares may be identified from records maintained by HeartWare or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

304. Lead Plaintiff's claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

305. Lead Plaintiff will fairly and adequately protect Class members' interests and has retained competent counsel experienced in class actions and securities litigation.

306. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about MVAD, including its safety profile and commercial viability, and HeartWare's manufacturing, testing, and validation processes;

(c) whether Defendants acted with scienter; and

(d) to what extent the members of the Class have suffered damages, as well as the proper measure of damages.

307. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation makes it impossible for such members to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

XII. CLAIMS FOR RELIEF

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5 PROMULGATED THEREUNDER (Against All Defendants)

308. Lead Plaintiff repeats and re-alleges each and every allegation set forth above as if fully set forth herein.

309. This Count is asserted on behalf of all members of the Class against Defendants HeartWare and Godshall for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

310. During the Class Period, Defendants disseminated or approved the false statements specified below, among others, which Defendants knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

311. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts,

practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of HeartWare common stock during the Class Period. As detailed herein, the misrepresentations contained in, or the material facts omitted from, those statements included, but were not limited to, HeartWare's efforts to remediate the manufacturing, testing, and validation deficiencies identified in the Warning Letter, their success in remediating those deficiencies, the progress of the CE Mark trial, and the safety profile and commercial viability of MVAD.

312. Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiff and the Class; made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with a severely reckless disregard for the truth; and employed devices and artifices to defraud in connection with the purchase and sale of HeartWare securities, which were intended to, and did: (a) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, HeartWare's efforts to remediate the manufacturing, testing, and validation deficiencies identified in the Warning Letter, their success in remediating those deficiencies, the progress of the CE Mark trial, and the safety profile and commercial viability of MVAD; (b) artificially inflate and maintain the market price of HeartWare securities; and (c) cause Lead Plaintiff and other members of the Class to purchase HeartWare securities at artificially inflated prices and suffer losses when the true facts became known.

313. Defendant HeartWare is liable for all materially false and misleading statements made during the Class Period, as alleged above, including:

(a.) Statements made during HeartWare's conference calls, including:

i. Defendant Godshall's false statements made during the William Blair & Company Growth Stock Conference on June 10, 2014;

ii. Defendant Godshall's false statements made during the Goldman Sachs Healthcare Conference on June 12, 2014;

iii. Defendant Godshall's false statements made during the second quarter 2014 earnings call on July 31, 2014;

iv. Defendant Godshall's false statements made during the third quarter 2014 earnings call on October 30, 2014;

v. Defendant Godshall's false statements made during the Canaccord Genuity Medical Technologies & Diagnostics Forum on November 20, 2014;

vi. Defendant Godshall's false statements made during the Oppenheimer Healthcare Conference on December 10, 2014;

vii. Defendant Godshall's false statements made during the fourth quarter and full year 2014 earnings call on February 26, 2015;

viii. Defendant Godshall's false statements made during the Raymond James Institutional Investor Conference on March 3, 2015;

ix. Defendant Godshall's false statements made during the Barclays Healthcare Conference on March 10, 2015;

x. Defendant Godshall's false statements made during the first quarter 2015 earnings call on April 30, 2015;

xi. Defendant Godshall's false statements made during the Goldman Sachs Healthcare Conference on June 11, 2015;

xii. Defendant Godshall's false statements made during the second quarter 2015 earnings call on July 30, 2015;

xiii. Defendant Godshall's false statements made during the Cannacord Genuity Growth Conference on August 13, 2015;

xiv. Defendant Godshall's false statements made during the Valtech Transaction call on September 1, 2015;

xv. Defendant Godshall's false statements made during the Wells Fargo Healthcare Conference on September 9, 2015;

xvi. Defendant Godshall's false statements made during the third quarter 2015 earnings call on October 29, 2015;

xvii. Defendant Godshall's false statements made during HeartWare's International Analyst and Investor Meeting on November 5, 2015;

xviii. Defendant Godshall's false statements made during the Credit Suisse Healthcare Conference on November 11, 2015;

xix. Defendant Godshall's false statements made during the Canaccord Genuity Medical Technology & Diagnostics Forum on November 19, 2015;

xx. Defendant Godshall's false statements made during the Piper Jaffray Healthcare Conference on December 1, 2015; and

xxi. Defendant Godshall's false statements made during the Oppenheimer Healthcare Conference on December 8, 2015.

(b.) Statements made in HeartWare's SEC filings, including:

i. HeartWare's February 26, 2015 press release, filed on Form 8-K, titled "HeartWare International Reports $73.2 Million In Fourth Quarter 2014 Revenue; 38% Increase From Fourth Quarter 2013";

ii. HeartWare's July 20, 2015 press release, filed on Form 8-K, titled "HeartWare International Announces First Human Implants Of The MVAD® System In CE Mark International Clinical Trial";

iii. Statements posted on HeartWare's website on October 12, 2015, filed on Form 8-K on October 13, 2015; and

iv. HeartWare's October 29, 2015 press release, filed on Form 8-K, titled "HeartWare International Reports Third Quarter 2015 Results."

314. Defendant Godshall is liable for the false and misleading statements he made and for which he was responsible, as set forth above, including:

(a.) Statements Godshall made during HeartWare's conference calls, including:

i. Defendant Godshall's false statements made during the William Blair & Company Growth Stock Conference on June 10, 2014;

ii. Defendant Godshall's false statements made during the Goldman Sachs Healthcare Conference on June 12, 2014;

iii. Defendant Godshall's false statements made during the second quarter 2014 earnings call on July 31, 2014;

iv. Defendant Godshall's false statements made during the third quarter 2014 earnings call on October 30, 2014;

v. Defendant Godshall's false statements made during the Canaccord Genuity Medical Technologies & Diagnostics Forum on November 20, 2014;

vi. Defendant Godshall's false statements made during the Oppenheimer Healthcare Conference on December 10, 2014;

vii. Defendant Godshall's false statements made during the fourth quarter and full year 2014 earnings call on February 26, 2015;

viii. Defendant Godshall's false statements made during the Raymond James Institutional Investor Conference on March 3, 2015;

ix. Defendant Godshall's false statements made during the Barclays Healthcare Conference on March 10, 2015;

x. Defendant Godshall's false statements made during the first quarter 2015 earnings call on April 30, 2015;

xi. Defendant Godshall's false statements made during the Goldman Sachs Healthcare Conference on June 11, 2015;

xii. Defendant Godshall's false statements made during the second quarter 2015 earnings call on July 30, 2015;

xiii. Defendant Godshall's false statements made during the Cannacord Genuity Growth Conference on August 13, 2015;

xiv. Defendant Godshall's false statements made during the Valtech Transaction call on September 1, 2015;

xv. Defendant Godshall's false statements made during the Wells Fargo Healthcare Conference on September 9, 2015;

xvi. Defendant Godshall's false statements made during the third quarter 2015 earnings call on October 29, 2015;

xvii. Defendant Godshall's false statements made during HeartWare's International Analyst and Investor Meeting on November 5, 2015;

xviii. Defendant Godshall's false statements made during the Credit Suisse Healthcare Conference on November 11, 2015;

xix. Defendant Godshall's false statements made during the Canaccord Genuity Medical Technology & Diagnostics Forum on November 19, 2015;

xx. Defendant Godshall's false statements made during the Piper Jaffray Healthcare Conference on December 1, 2015; and

xxi. Defendant Godshall's false statements made during the Oppenheimer Healthcare Conference on December 8, 2015.

(b.) Statements made in HeartWare's SEC filings, including:

i. HeartWare's February 26, 2015 press release, filed on Form 8-K, titled "HeartWare International Reports $73.2 Million In Fourth Quarter 2014 Revenue; 38% Increase From Fourth Quarter 2013";

ii. HeartWare's July 20, 2015 press release, filed on Form 8-K, titled "HeartWare International Announces First Human Implants Of The MVAD® System In CE Mark International Clinical Trial";

iii. Statements posted on HeartWare's website on October 12, 2015, filed on Form 8-K on October 13, 2015; and

iv. HeartWare's October 29, 2015 press release, filed on Form 8-K, titled "HeartWare International Reports Third Quarter 2015 Results."

315. As described above, Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations and omissions of material facts set

forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them.

316. Lead Plaintiff and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for HeartWare securities, which inflation was removed from the stock when the true facts became known. Lead Plaintiff and the Class would not have purchased HeartWare securities at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by these Defendants' false and misleading statements.

317. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their purchases of HeartWare securities during the Class Period.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT (Against Defendant Godshall)

318. Lead Plaintiff repeats and re-alleges each and every allegation set forth above as if fully set forth herein.

319. This Count is asserted on behalf of all members of the Class against Defendant Godshall for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

320. During his tenure as CEO and a director of HeartWare, Defendant Godshall was a controlling person of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of his position of control and authority as CEO and a director of HeartWare, Defendant Godshall had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. Defendant Godshall was able to and did control, directly and indirectly, the content of the public

statements made by HeartWare during the Class Period, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

321. In his capacity as a senior corporate officer of the Company, and as more fully described above, Defendant Godshall had direct involvement in the day-to-day operations of the Company, in, among other things, reviewing and managing its efforts to address the Warning Letter and remediating relevant internal functions, supervising the Company's efforts to commercialize MVAD, regulatory compliance, and reviewing and approving the Company's public statements. As a result of the foregoing, Defendant Godshall was a controlling person of HeartWare within the meaning of Section 20(a) of the Exchange Act.

322. As set forth above, HeartWare violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person of HeartWare and as a result of his own aforementioned conduct, Defendant Godshall is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiff and the other members of the Class who purchased or otherwise acquired HeartWare common stock.

323. As a direct and proximate result of Defendant Godshall's conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of HeartWare securities.

XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment as follows:

(a) Declaring the action to be a proper class action pursuant to Fed. R. Civ. P. 23;

(b) Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Awarding such equitable, injunctive and other relief as the Court may deem just and proper.

XIV. JURY DEMAND

Lead Plaintiff hereby demands a trial by jury.

Dated: June 29, 2016

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP

/s/ John Rizio-Hamilton
John Rizio-Hamilton
Abe Alexander
1251 Avenue of the Americas
New York, New York 10020
Telephone: (212) 554-1400
Facsimile: (212) 554-1444
Email: johnr@blbglaw.com
Email: abe.alexander@blbglaw.com

Counsel for Lead Plaintiff St. Paul Teachers' Retirement Fund Association and Lead Counsel for the Class